Les Laboratoires Servier v Apotex Pty Ltd [2016] FCAFC 27

FEDERAL COURT OF AUSTRALIA

BENNETT, BESANKO AND BEACH JJ

THE COURT:

INTRODUCTION

1 Les Laboratoires Servier is the Patentee and Servier Laboratoires (Aust.) Pty Ltd the exclusive licensee (together, **Servier** or **the Patentee**) of Australian Patent No. 2003200700 (**the Patent**) entitled "New salt of perindopril and pharmaceutical compositions containing it". Apotex Pty Ltd (**Apotex**) sought revocation of the Patent on a number of grounds, only some of which are relevant to the appeal.

2 The appeal concerns orders made by the primary Judge in four separate decisions: [2013] FCA 1426 (**the best method decision**), (2014) 107 IPR 95 (**the declaration decision**), (2015) 111 IPR 160 (**the amendment decision**), and (2015) 324 ALR 549 (**the costs decision**). The best method decision contained his Honour's reasons for determining that the Patent was liable to be revoked for failure to comply with s 40(2)(a) of the *Patents Act 1990* (Cth) (**the Act**). The declaration decision concerned the form of the declaration made consequently to the best method decision. The amendment decision contained his Honour's reasons for refusing Servier's application to amend the Patent following upon his Honour's declaration as to revocation. The costs decision contained his Honour's reasons for ordering the successful applicant for revocation and the successful opponents of amendment (Apotex and Actavis Pty Limited (**Actavis**)) to pay 66.67% of Servier's costs of the revocation proceedings and to pay 60% of Servier's costs of its unsuccessful application to amend the Patent.

3 Apotex has filed a cross-appeal concerning the form of declaration made by the primary Judge as to revocation. Pursued by way of notice of contention are representations asserted by Apotex to be misrepresentations or false suggestions, which the primary Judge characterised as "the shelf life representation" and "the temperature representation". Apotex argues that the Patent was obtained by these representations and, accordingly, should be revoked on this basis.

THE APPEAL IN RESPECT OF THE BEST METHOD DECISION

4 Servier points out that certain grounds for revocation under the Act were not relied on before the primary Judge or are not pressed on appeal, in particular:

- There is no alleged false representation as to the promises of the benefits of the invention.
- It is not suggested that the invention as claimed did not fulfil its promises.

- There is no allegation of lack of utility.
- There is no asserted invalidity for lack of sufficiency, in the sense that it is accepted that there is sufficient description to enable a person of ordinary skill to work the invention as claimed. Thus, this requirement of s 40(2)(a) of the Act is fulfilled.

The Patent

5 The claims of the Patent relevant to the appeal from the best method decision are claims 1 and 2, namely:

Claim 1:

> *The arginine salt of perindopril and its hydrates.*

Claim 2:

> *Pharmaceutical composition comprising, as active ingredient, the arginine salt of perindopril and its hydrates, in combination with one or more pharmaceutically acceptable excipients.*

6 Claims 8 to 11 are relevant to the amendment decision but the proposed amendment to delete those claims is not opposed.

7 As the specification explains, the claimed invention relates to a new salt of perindopril, a compound known especially for the treatment of arterial hypertension and heart failure. Perindopril was the subject of a previous patent where it was described in a non-salt form. When addition salts with a pharmaceutically acceptable base or acid were mentioned in the previous patent by way of example, the sodium salt or the maleate was given. The specification of the Patent explains the difficulty in finding a pharmaceutically acceptable salt having not only good bioavailability but also adequate stability to be suitable for the preparation and storage of pharmaceutical compositions. The specification then describes difficulties with earlier salt forms in terms of stability. A particular form is said to have exhibited the best stability compared to other forms studied, being the *tert*-butylamine salt (perindopril erbumine) but, the specification states, even that form was not capable of providing a complete solution to the problems of the product's lack of sufficient stability to heat and humidity, in particular, instability resulting in a shorter shelf life and the need for additional packaging measures. Reference is made to *'the intrinsic fragility of perindopril'*.

8 The specification states that numerous salts were studied and that the salts customarily used in the pharmaceutical sector proved to be unusable. The claimed invention, the arginine salt of perindopril, was said to have *'entirely unexpected advantages over all the other salts studied'*. The arginine salt of perindopril is said preferentially to be the salt of natural arginine (L-arginine). The specification also states that the pharmaceutical compositions according to the invention will preferably be immediate-release tablets. The specification describes long-term stability studies of perindopril arginine, the results of which are presented in tabular form:

Conditions **6 months**	***tert*-Butylamine salt of perindopril** **Percentage remaining (%)**	**Arginine salt of perindopril** **Percentage remaining (%)**
25°C 60% R.H.	101.0	99.5
30°C 60% R.H.	94.4	98.1
40°C 75% R.H.	67.2	98.6

9 As to the preparation of the arginine salt, the specification states:

> *The arginine salt used in this study is the L-arginine salt. It has been prepared according to a classical method of salification of organic chemistry.*

10 Relevantly to the appeal from the best method decision, it can be noted that there is no other detail of the preparation of the claimed arginine salt and that the reference is to *'a'* classical method of salification, with no specific method referred to by way of citation or otherwise.

The best method issue

11 Section 40(2)(a) of the Act (as set out in Reprint 3 as agreed to be applicable) provides that the complete specification must:

> *(a) describe the invention fully, including the best method known to the applicant of performing the invention;*

12 The appeal from the best method decision centres on the finding that s 40(2)(a) included a requirement that the patentee disclose the best method known to the patentee of performing the invention over and above the requirement of sufficiency as set out above, and that Servier had failed to comply with that obligation (**the best method issue**).

The primary Judge's decision

13 The primary Judge determined (at [63]) that the hypothetical person skilled in the art, the skilled addressee, was a non-inventive chemist with scientific qualifications working in a drug development context, whose routine work involved the formulation and making of salts for use in pharmaceutical products. His Honour also stated that it is likely that such a person would have worked in a team, where the person would be conversant with the principles and general practicalities of salt making and salt selection as well as the methods of pharmaceutical tablet formulation and composition.

14 In dealing with the question of novelty, as to which there is no appeal, his Honour observed at [75] that:

> *'All the experts agreed that they would not try arginine in a first salt-screen to make a new perindopril salt. The unpredictability of successfully making a salt with any counter-ion, let alone one that is pharmaceutically acceptable, requires a person skilled in the art to engage in a selection process.'*

15 His Honour pointed out at [97] that the experts, as persons skilled in the art, suggested that a number of options could be explored, for example, new salts. At [98] his Honour referred to the evidence of Professor Byrn, an expert witness relied on by Servier, who said that there were at least five methods of crystallisation that a person skilled in the art could use and that *'these involved potentially many different variables such as the choice of one or more solvents, heating rate, maximum temperature, whether, and how long, to cool the mixture, the time allowed for crystals to form, type of crystallisation vessel, its surface volume and the mixing rate, to name only some. Each variable can affect the result'*.

16 At [99] his Honour recorded Professor Byrn's evidence that each crystal structure in which a salt exists can affect a salt's stability characteristics in a way that is not predictable and that differences in the form of polymorphs or hydrates can also affect stability. There is no certainty

that any particular counter-ion will be able to make a salt with an active pharmaceutical ingredient (**API**) and, secondly, if it does, what the properties of that salt will be (at [100]).

17 The primary Judge also noted (at [105]) that the experts agreed that *'successful salt making is sometimes dependent on the maker's intuitions and interventions with stirring or leaving the mixture.'* His Honour noted that Dr Spargo, on whom Apotex relied, accepted the description that salt making was *'something of a dark art and you can do it at different times and get different results'*. Dr Spargo also agreed that changes in formulation in the salt formation process, or of the tablets, could produce different results and that until a product was tested in tablets one would not know if the new salt would be an improvement on the existing one.

18 Again, as part of his conclusion on obviousness, which centred on the choice of arginine, his Honour made reference to the conclusion that there are many pitfalls and blind alleys in the making of pharmaceutically acceptable salts. His Honour concluded that he was not satisfied that the selection of arginine as a counter-ion to use in making a salt of perindopril was obvious.

19 Turning to a consideration of fair basis, the primary Judge made a number of observations also relevant to questions of best method, although not considered in that context. Thus, there is an advantage if a hydrated salt is highly crystalline and, where a pharmaceutical salt could have more than one form, the properties of each form will only be known after empirical studies or testing of the compound (at [128]-[129]).

20 If perindopril and arginine are subjected to a classical method of salification, the nature of the precipitate that will form (i.e. the form of the crystalline salt, whether it is anhydrous, a monohydrate, dihydrate, polymorph, etc.) could be influenced by the solvent or solvents used and the temperatures of the process. For example, a hydrate could form after salification while the salt was being stored and, if water was the solvent that was present, the resulting salt could be a hydrate.

21 It is not necessary to consider details of this for the purposes of the best method issue. Rather, they are comments relevant to the variables that can arise using a classical method of salification. The skilled addressee would know that classical salification can use water, which could result in a hydrate form of the salt (at [137]).

22 His Honour also concluded that the skilled addressee reading the specification as a whole would understand that the Patentee was making a real and reasonably clear disclosure that the invention consisted of the arginine salt and the various forms that it could take, namely

hydrates, as well as the salt and its hydrates in pharmaceutical compositions. The inventor had not disclosed the, or any particular, hydration state of the salt as being a feature of the invention. As his Honour stated (at [140]), the hydration state was not a feature of the invention. Rather, the invention was the salt in all of its potential hydration states, including a state where it was not a hydrate at all, which would be understood by the skilled addressee. The skilled addressee reading the specification as a whole would understand that, by claim 2, the invention extended to the salt and its hydrates in pharmaceutical compositions.

23 As to the disclosure that the arginine salt was prepared according to a classical form of salification of organic chemistry, the experts agreed that a skilled addressee knew that a salt could be produced in this way, using more than one such method. They also agreed that the resulting substance could be in a hydrated form, depending on the precise method used, but that it would be necessary to test the substance to ascertain whether it was a hydrate and what its properties were (at [141]). One of the expert witnesses, Professor Evans, had said that *'irrespective of whether or not there are different crystal forms of a salt,* ***it is still the salt****'* (original emphasis) and that in theory, perindopril arginine could come in several forms.

24 At [142] the primary Judge said:

> *'The first joint expert report explained that once the skilled addressee read that perindopril arginine could be produced by a classical method of salification,* first*, he or she would expect to be able to make the salt and,* secondly*, that there are many parameters that could influence the solid form of the salt that might be obtained from such a classic salification. I infer that the skilled addressee would understand that the consistory clause when read with the specification as a whole in light of the common general knowledge, disclosed that the form of the salt so produced (i.e. whether a hydrate or not) made no difference. Hence, the claims for the hydrates were fairly based on the matter described in the specification.'*

25 Apotex relied upon the absence in the specification of a method of preparing a pharmaceutical composition containing perindopril arginine so as to achieve the results of the long-term stability study described in the specification. His Honour set out the relevant descriptions from the specification concerning performance of the invention that are contained in the Patent, as follows (at [143]):

- (in the consistory clause), *'[t]he present invention relates to the arginine salt of perindopril, its hydrates and also to the pharmaceutical compositions comprising it'* (p 2 lines 15-16);
- the arginine salt is *'preferentially the salt of natural arginine (L-arginine)'* (p 2 line 17);

- the pharmaceutical compositions *'comprise the arginine salt of perindopril together with one or more, non-toxic, pharmaceutically acceptable and appropriate excipients'* (p 2 lines 18-20);
- those compositions will preferably be immediate release tablets (p 3 lines 1-2);
- the amount of the salt contained in the compositions is between 0.2 and 10 mg, preferentially from 1 to 10 mg (p 3 lines 6-8); and
- *'*[*t*]*he arginine salt used in this study is the L-arginine salt. It has been prepared according to a classical method of salification of organic chemistry'* (p 3 lines 22-23).

The parties do not suggest that any other parts of the specification are relevant to the best method issue.

26 His Honour noted at [145] that both the inventor, Gerard Damien, and Servier knew that perindopril arginine had been prepared in 1986 and 1991, using slightly different classical salifications. Neither of those methods, known to the Patentee, was referred to in the specification. Mr Damien gave evidence as to the method used in 1986 to make an initially small quantity of perindopril arginine (**the 1986 method**). The assistant who had been directed to make that compound chose to utilise a two stage process involving:

- A salt-break in which perindopril erbumine was converted, or broken down, so as to extract a quantity of perindopril in a white crystalline form.
- Immediate use of the freeform perindopril with L-arginine in nearly equal proportions, where those three ingredients were mixed in a flask resulting in a "semi-limpid solution" which was stirred for 15 to 20 minutes and evaporated until dry, producing a crystalline residue. That residue was "retaken" in a "trituration" using anhydrous ether.

27 The experts explained that the process of trituration can be used if no direct crystallisation or precipitation of a salt occurs after the initial mix of ingredients (here, perindopril and arginine) in the solvent (here, permuted water). The resulting solution is evaporated to a low volume or until it is dry. That may yield either a solid or a concentrate. The concentrate may be in a form described by the experts as a "gum" or "glass" or a "foam". Trituration is used with the intention of converting such a concentrate into a solid that is potentially useable. Trituration involves mixing the concentrate into a solution with a new, volatile solvent that "retakes" the concentrate.

28 His Honour described retaking at [148]:

> *'For example, after the initial mixing, the resulting solid or concentrate may stick to the sides of the mixing flask. The introduction of a new solvent "retakes" that substance into a liquid form. This can separate out impurities that could have impeded the formation of a crystalline salt, so that when the new solvent evaporates, the scientist hopes to achieve a useful crystalline salt. If different solvents are used in triturations, different solid forms of the salt may result, such as a polymorph, hydrate or solvate. The experts also noted that in a classical salification there are many parameters, including the choice of solvent, that could influence the solid form of any perindopril arginine that might be obtained from such a process.'*

29 His Honour then noted that the experts agreed that while this technique may be useful in laboratory conditions, it is not practicable on a large scale or in commercial production. As the 1986 method was carried out by Servier, after the trituration step the product was filtered under a vacuum, washed again with anhydrous ether and dried again in a desiccator under another vacuum to produce a white crystalline substance, being perindopril arginine.

30 His Honour also recorded that in 1991, a different method was used, directed by Mr Damien (**the 1991 method**), to prepare another salt-screen which included perindopril arginine. This method involved lyophilisation, another standard procedure, which comprises freeze drying as a way of removing water from the material. The salification in the 1991 method utilised quantities and proportions of perindopril and L-arginine that were different from those used in the 1986 method. In the 1991 salification, the assistants mixed the perindopril, L-arginine and water, dissolved the two solids in the water and then filtered the mixture to eliminate insoluble particles. That filtered solution was then lyophilised, the residue dissolved in anhydrous ethyl ether, stirred and filtered again, before being dried in a desiccator to yield a white crystalline product.

31 Mr Damien's evidence was that for the purposes of a later study in 2000, he prepared perindopril arginine with the same excipients and quantities as were used for Servier's commercial Coversyl product, in which perindopril erbumine was the API. His Honour said at [152] that there was no clear evidence of the details of the salification ingredients or method used in the preparation of perindopril arginine used in that study, but said that it was likely that the method repeated the 1991 method.

32 His Honour noted at [153] that the experts agreed that the selection of different methods and parameters can influence the precipitation or crystallisation of salt as the outcome of the various classical methods of salification. His Honour then said:

> *'[t]hus, there was no certainty that any particular method within the range of classical*

methods, or the variety of choices, such as solvents, duration, or temperatures within a selected method would necessarily produce a crystalline salt or a particular salt form (such as a hydrate) that could be used in a pharmaceutical composition.'

33 His Honour noted further at [154] that the experts agreed that if an API is hygroscopic and takes up water, there is a potential for its crystal structure to change to one or more new crystalline forms, that will have different physiochemical properties to those of the anhydrous form. Those differences may not be large but they could affect the substance's dissolution and solubility, which in turn has the potential to affect the bioavailability. However, his Honour noted that it is also possible that water sorption will have no effect whatever and so will not cause any problem.

34 The experts agreed that each of the procedures used by Mr Damien's assistants in the 1986 and 1991 methods was a standard classical procedure for salification. His Honour added that the experts stated that the formulation of an API into a pharmaceutical product introduces factors that may compromise the final product's stability, such that the ingredients and methods used to make a pharmaceutical composition with an API can have *'significant consequences for the end product's stability'* (at [156]).

35 The primary Judge set out Servier's arguments, which may be summarised as follows:

- It was necessary that Apotex prove that the alleged non-disclosed best method provided a result that was better than the result of the method disclosed in the complete specification.
- A method was disclosed in the specification because Apotex did not contend that the Patent was revocable for lack of utility, thus accepting that the Patent disclosed a form of the invention that worked to fulfil the promise in the specification.
- Accordingly, a method was disclosed and Apotex had to prove that one or both of the 1986 or 1991 methods of salification was a better method than the one disclosed.
- Apotex had not established that any of the variations between the 1986 and 1991 methods had any effect on the resulting perindopril arginine.
- There was no evidence of a use of a classical method of salification that had produced an arginine salt of perindopril that was materially different or worse than the salts produced by the 1986 or 1991 methods.

- While the experts expressed a unanimous opinion that differences in classical methods of salification and parameters might produce different results, this was a hypothesis which Apotex had not proven.
- Mr Damien gave unchallenged evidence that an inherent property of arginine was that it was not volatile and that the stability of perindopril arginine was not affected by its hydration state.
- There was no suggestion of any material difference between the perindopril arginine produced by the 1986 and 1991 methods.
- There was no evidence that the methods that Servier had used to prepare the arginine salt were special or particular.
- There was evidence from Professor Byrn that classical salification would tend to make the most stable form.
- A patent applicant had no obligation to disclose the best method of making an invention, as opposed to the best method for performing or carrying it out.
- There is no need to disclose a method of making a particular form of the invention if it is sufficiently described, in the sense that a skilled addressee could make it having been told what the form is.
- As the invention was not limited to a particular form of perindopril arginine, the complete specification did not have to describe any form.
- A patent applicant has no obligation to disclose a method of performing the invention beyond providing a full description sufficient to enable a skilled addressee to make something within each claim.
- The patent applicant only has an obligation to disclose a best method of performing the invention where there is in fact a *'best method'* and it is *'known to the applicant'*.

36 The primary Judge rejected Servier's arguments which, he said (at [163]):

> *'... ignored the express requirement in s 40(2)(a) that the description in the complete specification include the best method of performing the invention known to the applicant. The statute does not given the applicant any option not to comply with that requirement. If the applicant knows only one method, that is the method that must be described; if more than one, the applicant must include the best one known to him, her or it.'*

37 The primary Judge added that the requirement imposed by s 40(2)(a) that the complete specification describe the best method known to the patentee of performing the invention is fundamental, and that it supplements the co-ordinate requirement in s 40(2)(a) that the complete specification also describe the invention fully. The primary Judge observed that it is not necessary that the best method be identified as such in a complete specification as long as the method is disclosed in the complete specification and is the best method known to the applicant (*Pfizer Overseas Pharmaceuticals v Eli Lilly & Co* (2005) 68 IPR 1 at [374]). Depending on the invention, that requirement may be satisfied in different ways, such as a detailed description of a preferred embodiment, reference to drawings or structures, or specific process conditions or chemical formulations (*Firebelt Pty Ltd v Brambles Australia Ltd* (2000) 51 IPR 531 at [53]).

38 The primary Judge, in his reasons at [167] and following, identified a number of other matters relevant to a consideration of whether an applicant has complied with the statutory obligation to disclose the best method of performing the invention:

- The complete specification must disclose each essential element or feature for performing the invention, even if a skilled addressee would know or could readily ascertain that element (*Norton and Gregory Ltd v Jacobs* (1937) 54 RPC 271 at 277).
- The requirement is to describe every essential element or feature for performing the invention, as opposed to what a skilled addressee would know from the description actually given in the complete specification about well-known matters (*Expo-Net Danmark A/S v Buono-Net Australia Pty Ltd (No 2)* [2011] FCA 710 at [14] per Bennett J).
- The parties seeking revocation must prove that the patentee knew of a better method than the one disclosed at the time of filing the complete specification (*Expo-Net* at [15]).
- The applicant for revocation must show that the method which the patentee failed to disclose is a method of performing the invention; that the method is in fact a better method; that the method was known to the patentee at the time when the application was lodged; that the method is not disclosed in the specification; and that the patentee knew that the method was better than the method described in the specification (*Expo-Net* at [16]).
- The specification is not read in the abstract but from the vantage point of a skilled addressee.

39 The primary Judge said that the question in the present case was, in essence, whether Servier's description in the complete specification of preparing perindopril arginine from L-arginine and perindopril according to a classical method of salification of organic chemistry satisfied the requirement in s 40(2)(a) to state the best method of performing the invention known to it.

40 The primary Judge rejected the argument that the description of best method had to include the initial salt break, as the obtaining of the ingredients that resulted from that methodology formed no part of the invention.

41 His Honour accepted Servier's argument that whatever the particular crystalline form of the arginine salt, it was intended to be part of the invention. The key question, really, concerned the choice that the skilled addressee had to make of parameters to get a result within the ambit of the asserted monopoly.

42 His Honour then noted the following matters:

- The skilled addressee would have understood that the complete specification disclosed that the excipients used in the study were the same for the two salts and that the only variable was the quantity of the different salts.
- The reference to preparation according to a classical method of salification was *'pregnant with ambiguity'*.
- The result from a classical salification is sensitive to the choices of solvent and many other parameters.
- While each of the 1986 and 1991 methods produced a useful result, there was a lack of detail of either method in the complete specification, leaving the skilled addressee to speculate about the parameters, including the choice of solvents.

43 The primary Judge rejected Servier's argument that the onus was on Apotex to prove that a skilled addressee using another classical method of salification would have achieved, or did achieve, a worse result than those achieved in the 1986 or 1991 salifications. His Honour pointed out that Servier was aware of the vagaries of classical salification and aware that the selection of parameters, including solvents, could affect the result.

44 His Honour concluded that there was insufficient detail to provide a skilled addressee with directions necessary to perform the invention without undertaking potentially extensive trial and error experimentation. While this may have gone more to sufficiency than to best method,

his Honour continued to state that a reference to a classical method of salification did not describe the best method of performing the invention. His Honour also stated that the opinion of the six experts was that the variety of choice as to methods and parameters available for selection within classical salification was not merely a hypothetical, but unproven, lacuna in the disclosure made in the complete specification of the best method. His Honour concluded that the mere reference to use of a classical method of salification was *'wholly inadequate'* and that the bare description of a classical method of salification *'does not allow the skilled addressee to follow a routine process of deduction from that description because it leaves open too many variables'*.

45 At [180], the primary Judge distinguished between the requirement to include sufficient information to enable a skilled addressee to work the invention and the additional obligation to describe the best method known to the patentee. His Honour found that Mr Damien knew that the 1986 and 1991 methods created the arginine salt in a useable form and that, as a person skilled in the art, he knew that there were many alternatives available from which to choose. His Honour made the additional finding that Mr Damien knew that some methods were likely not to be as good as others.

46 The primary Judge concluded that the 1986 and 1991 methods were better than what was disclosed in the Patent, because they eliminated the risks as to time and resources needed in the trial and error experimentation potentially involved for a skilled addressee following the variety of possible, but unspecified, methods of classical salification. His Honour also found that there were many potential choices available in classical salifications that may, but need not, lead to the successful preparation of a crystalline arginine salt or hydrate. While the method described in the Patent was sufficient for the skilled addressee to produce something within each claim, his Honour held that it fell short of disclosing the best method of doing so, that is, the best method known to the Patentee that yielded an arginine salt that could be used in a pharmaceutical composition as required by claim 2.

47 Servier had used a particular method, or methods, of classical salification and parameters that produced a guaranteed result, whereas the complete specification described a broad and very general method of performing the invention that left the choice from the large range of variables to chance. His Honour concluded that by omitting a sufficient description of a successful method that it had employed, Servier had failed to describe in the complete specification the

best method known to it of performing the invention. Accordingly, the complete specification did not satisfy one of the essential requirements of s 40(2)(a) of the Act.

The issues on the appeal

48 The parties agree that Servier satisfied the test enunciated by the High Court in *Kimberly-Clark Australia Pty Limited v Arico Trading International Pty Limited* (2001) 207 CLR 1, namely that s 40(2)(a) requires a disclosure that would enable the addressee of the specification to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty (***the* Kimberly-Clark *test***).

49 Servier's submissions are directed to three issues:

(1) Whether the statutory test in s 40(2)(a) is satisfied if the *Kimberly-Clark* test of sufficiency of description is satisfied. Servier says that there is no residual requirement to specify any method of performing an invention where that test is satisfied. Such a need only exists where specification of a method is required to enable the skilled addressee to produce something within the claim without new inventions or additions or prolonged study of matters presenting initial difficulty.

(2) Whether any residual best method requirement, if it exists, is satisfied by the identification of the essential integers of the product. Servier submits that a method of *making* an invention is not a method of performing the invention as required by the statutory test.

(3) Whether, as Servier submits, a method of making the product can only be the "best" if it is demonstrated that such method produces something which is in fact better than that made by the method disclosed in the patent and known to be so by the patentee.

Issue 1: Section 40(2)(a) of the 1990 Act and the requirement to provide a best method of performing the invention

1. The pleading point

50 In the further amended particulars of invalidity, the ground of lack of best method is, relevantly, set out at [41]-[42] as follows:

> *41. Further, or in the alternative, if (which is not admitted) the process to make the perindopril arginine salt forms part of the inventive step described in the Arginine Patent, the specification does not describe the best method known to the Patentee of performing the invention as claimed in each claim of the Arginine Patent, being the means of making the perindopril arginine salt so as to obtain the alleged benefits of the invention.*

Particulars

...

(e) The confidential particulars set out in paragraph 49 in Annexure A to these Further Amended Particulars of Invalidity.

(f) The Applicant's case is that the Arginine Patent does not disclose the best method of performing the invention known to the Patentee because:

1. the Arginine Patent discloses no method of carrying out the matters referred to in paragraph 41 above; and

2. the Patentee knew at the date of filing the application of the Arginine Patent of at least one method for performing the matters referred to in paragraph 41 above as set out in the confidential particulars of paragraph 49 of Annexure A to these Further Amended Particulars of Invalidity.

(g) The Applicant does not rely on any method which the Patentee may have had other than the method described in paragraph 49 of Annexure A to these Further Amended Particulars of Invalidity.

42. Further, or in the alternative, if (which is not admitted) the process to make the perindopril arginine salt forms part of the inventive step described in the Arginine Patent, the specification does not describe the best method known to the Patentee of performing the invention as claimed in each claim of the Arginine Patent, as it does not describe which form or forms of perindopril arginine to make so as to obtain the alleged benefits of the invention.

Particulars

...

(d) The Applicant repeats the particulars at paragraph 41(f) and 41(g) above.

51 Servier takes issue with the scope of the pleaded ground as raised by Apotex. First, it says that, on its face, it is limited to an allegation of a lack of sufficiency. Secondly, it does not plead that the method in the Patent gives rise to a product that is inferior to that of the 1986 and 1991 methods of which Servier knew. The confidential particulars referred to the 1986 and 1991 methods, which are relevant to a claimed lack of best method and not to the *Kimberly-Clark* test. We reject Servier's 'pleading point'. The pleading is clearly directed to the wording of s 40(2)(a) referring to the best method of performing the invention. That is a clear pleading of

the failure to provide the best method known to the Patentee and is not limited to a sufficiency claim.

2. Is there a separate or "co-ordinate" requirement to provide the best method known to the patentee of performing the invention?

Servier's submissions

52 Servier accepts that the Patent disclosed no specific salification method of making the perindopril arginine salt. There is no dispute that the Patentee knew of the 1986 and 1991 methods. There is no separate best method argument based on claim 2 of the Patent. The parties agree that this question falls to be decided by consideration of claim 1.

53 Servier submits that, as there is no dispute that the *Kimberly-Clark* test was satisfied and that the primary Judge so held, Servier complied with its obligations under s 40(2)(a) of the Act. It says that in *Kimberly-Clark*, it was held that, in order to comply with s 40(2)(a), the specification must enable only one embodiment within each claim. If enablement can be provided by common general knowledge, there is no need to provide disclosure across the entire scope of the claim. Thus, if common general knowledge enables the skilled worker to make something within the claim, there is no requirement to make reference to any method at all of producing a product.

54 For the purposes of discussion of this issue, we will refer to the "sufficiency requirement" as the requirement that satisfies the *Kimberly-Clark* test and to the "best method requirement" as encompassing the words set out in the latter part of s 40(2)(a).

55 In summary, Servier's submission is as follows:

- one starts with the proposition that if any embodiment of the invention is enabled by the complete specification, that is sufficient;
- the best method requirement is a subset of the ordinary sufficiency requirement;
- there can be no additional requirement to provide a best method, as it would be inconsistent with the lack of the requirement to enable the best embodiment.

56 Servier draws on a number of decided cases to advance the following submissions:

- When the express reference to 'best method' was introduced into the *Patents Act 1952* (Cth) (**the 1952 Act**), the High Court (Dixon CJ, Kitto and Windeyer JJ) said, relevantly, in *Welch Perrin & Co Pty Limited v Worrel* (1961) 106 CLR 588 (at 609-

610) that the differences between s 40 of the 1952 Act and its predecessor s 36 of the *Patents Act 1903* (Cth) (**the 1903 Act**) were *'probably of no importance'* and that the main requirement is that a specification fully describes the invention and the manner in which it is to be performed.

- The reference to 'the best method known to the applicant of performing the invention' is part of the requirement to 'fully describe the invention', as indicated by the words 'including the best method' (*AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123 (at 128C) per McTiernan J).
- There were similar observations in *Lockwood Security Products Pty Limited v Doric Products Pty Limited* (2004) 217 CLR 274 (at [60]) and *Pfizer* per French and Lindgren JJ (at [343]) with Crennan J agreeing (at [408]) that *'the best method is an inclusion in the sufficiency criterion'*.
- In *Kimberly-Clark*, the High Court referred to *No-Fume Limited v Frank Pitchford & Co Limited* (1935) 52 RPC 231, where Romer LJ's discussion was in terms of the sufficiency requirement and said that this does not necessarily require a wealth of detail such as manufacturer's specifications. The UK Act there under consideration did not include a specific reference to 'best method', but instead required the patentee to describe the *'manner in which the invention [was] to be performed'*.
- In *DSI Australia (Holdings) Pty Limited v Garford Pty Limited* (2013) 100 IPR 19 at [334], Yates J said that a patentee's only obligation under s 40(2)(a) of the 1990 Act was captured by the *Kimberly-Clark* test.

57 Servier rejects the suggestion that the reference to best method was specifically added to provide for a separate enquiry. Servier relies upon the word 'including' in s 40(2)(a) to submit that there is no separate or additional requirement over that set out in the first part of the sub-section, which is subject to the *Kimberly-Clark* test.

58 In answer to the statutory requirement to give the 'best' method, Servier responds that it is directed to the proposition that if the knowledge cannot be supplied by common general knowledge, the patentee must inform the skilled reader of the best method known to the patentee of how to make the product. Servier acknowledges that this submission would mean that if there were enough information in the Patent to enable the person of ordinary skill to work the invention, then even if the patentee knew of a better method, it would not be obliged to disclose it.

The construction of s 40(2)(a) of the Act

59 A number of preliminary observations should be made. First, it must be assumed that all of the words of the section are given meaning. Secondly, fulfilment of the requirements must take into account the invention being described and claimed. That does not lend itself to the apparently easy, but superficial, distinction advanced by Servier, whereby inventions are divided into the categories of product and process. Thirdly, perhaps because the requirement involves a question of fact, being the knowledge of the patent applicant, there are not many cases that have centred on the principles of this aspect of the test compared to those that have considered the requirement of what is commonly called sufficiency, such as *Kimberly-Clark*. Accordingly, fourthly, in applying principles from decided cases on s 40(2)(a) and its equivalents, it is necessary to understand the issues there discussed and whether or not the reasons extended to a consideration of a statutory provision referring to the best method known to the applicant. Fifthly, there are a number of cases in the United Kingdom where this question and the principles behind the application of the best method requirement have been discussed. Clearly, they are not binding and are based on different statutory provisions. However, much of Australian patent jurisprudence on this and other patent issues was derived from British jurisprudence.

60 Before embarking on the submissions as to the requirement to provide the best method known to the patent applicant, it is necessary to consider the words of the statute. To reiterate:

> *A complete specification must describe the* ***invention*** *fully,* ***including*** *the best method known to the applicant of* ***performing the invention****.* (emphasis added)

61 Servier's submission is that the sufficiency requirement encompasses the best method requirement and that best method is a subset of sufficiency and enablement. Put another way, Servier contends that there is no separate, additional or "residual" best method requirement.

Provisional applications and complete specifications

62 The Act distinguishes between the obligation to describe the invention and the obligation to describe it fully, including the best method known to the patentee of performing the invention.

63 Different obligations of description of the invention exist for provisional and complete specifications. By s 40(1), a provisional application must describe the invention, but a complete specification must describe the invention fully including the best method known to the applicant of performing the invention (s 40(2)(a)). In a provisional application, the inventor

discloses the nature of the invention in order to protect the invention, but is provided with the opportunity to develop the invention before the date of filing.

64 The proposition underlying a separate and additional obligation on the part of the inventor filing a complete specification is that where an inventor in fact knows of a method at the time of filing the complete patent application, which has taken the methodology to a more satisfactory stage or provides more certainty so that the public may more quickly and easily utilise the invention for which a monopoly is granted, the inventor is under an obligation to disclose that method.

65 This statutory distinction has provided a basis for the consideration of whether the patentee is under an obligation to provide the best method over and above an obligation to describe the invention.

The cases dealing with a best method requirement in the filing of a complete specification after the filing of a provisional specification

66 A number of early cases in the United Kingdom concerning the filing of a complete specification have considered that obligation:

- In *Pneumatic Tyre Company Ltd v Leicester Pneumatic Tyre and Automatic Valve Company* (1899) 16 RPC 531 (at 541) Lord MacNaghten said that if an inventor discovers any better mode of carrying an invention into effect between filing a provisional specification and a complete specification *'he is bound to disclose it in the complete specification'*.
- As put by Lord Tenterden in *Crossley v Beverley* (1830) 1 WPC 112 (at 116) the patentee thereby *'renders it more complete'*.
- As put by Bailey J in *Crossley v Beverley* (at 117), if the inventor has made a discovery which will *'enable it better to effectuate the thing for which the patent was obtained, not only is he at liberty to introduce them into his patent, but …it is his bounden duty so to do'*.
- A patent will not be bad simply because a different mode of carrying out the same invention is described in the complete specification from that in the provisional specification: *Woodward v Sansum* (1887) 4 RPC 166 at 175. In that case, at 175, Cotton LJ said that where, after the filing of a provisional specification but before the filing of a complete specification, a patentee finds out improvements in the way of

carrying the invention into effect *'he is bound to give the public the benefit of what he has discovered as regards the mode of carrying the invention … into effect'*.

Cases on s 40(2)(a), its predecessors and equivalent provisions

67 Many of the authorities dealing with s 40(2)(a) of the 1990 Act and its predecessors, when properly understood, were considering the obligation to describe the invention fully, the sufficiency requirement. Rarely were cases specifically directed to the question of an obligation to provide the best method known to the applicant of performing the invention. As Blanco White pointed out, the best method requirement is not commonly advanced as a ground for revocation: Blanco White TA, *Patents for Inventions and the Protection of Industrial Designs* (5th ed, Stevens & Sons, 1983) (**Blanco White (5th ed)**) at [4-514]. In Terrell C and Corsellis DH, *The Law and Practice Relating to Letters Patent for Inventions* (7th ed, Sweet & Maxwell Ltd, 1927) at 135 under the heading 'Good Faith and Disclosure of Best Method', it is stated: *'[i]f a patentee suppresses anything, or if he misleads, or if he does not communicate all he knows, his patent is bad'*.

68 Many of the cases that purport to deal with s 40(2)(a) do not consider, and make no reference to, the question of the obligation to provide the best method. However, that does not mean that there is no such obligation. It means that the issue was not raised and that the argument was limited to the sufficiency requirement, the subject of the attack. This does not lead to the conclusion that those cases determined that the only obligation under that section was to comply with the *Kimberly-Clark* test, being a test of sufficiency.

69 Indeed, the same observation must be made of *Kimberly-Clark* itself. In that case, the issue was the sufficiency of the description of the invention, a baby's nappy with elasticised side pockets. Addressing this issue, the Court said (at [25]):

> *'[t]he question is, will the disclosure enable the addressee of the specification to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty?'*

Read in context, the Court was not thereby setting out a test for fulfilment of the requirements of s 40(2)(a) as a whole. It was not argued that the patentee had failed to disclose a best method. The test is directed at the issue of sufficiency of description.

70 As noted above, the Australian approach has followed from the principles established in the United Kingdom.

71 In *British Dynamite Company v Krebs* (1896) 13 RPC 190, Lord Hatherley said that where a large field for experiment was left open and the inventor had known of the existence of the best material at the time of filing, where that material was better than other materials specified, then the inventor was bound to give the best means at the inventor's disposal in order to achieve the result. It would have been an objection to the patent to say that the inventor, *'being in possession of the best mode of producing the most valuable dynamite, had not informed the public of that method'*. This obligation was discussed separately to the question of sufficiency, namely whether or not the description was sufficient to enable the ordinary workman to make and use dynamite. In the legislation in force at that time there was no explicit best method requirement; the patentee was obliged to describe the invention's 'manner of performance'.

72 The link between the extent of the obligations of disclosure and the nature of the invention was made early. For example, in *Edison & Swan Electric Light Company v Holland* (1889) 6 RPC 243 at 279, the Court of Appeal said that the patentee must state *'in what manner the patented invention is to be performed'* so that others know how practically to avail themselves of the invention when the patent is expired: *'how they are to do what is necessary to carry out the new invention'*, that is, how the invention is to be performed.

73 In *Vidal Dyes Syndicate Ltd v Levinstein Ltd* (1912) 29 RPC 245 at 265 (cited by the Full Court in *Firebelt*), the Court of Appeal differentiated between two duties incumbent upon a patentee, as provided in the statute. First, the obligation by which the patentee must *'particularly describe and ascertain the nature of the invention'* and secondly, that by which the patentee must *'particularly describe and ascertain 'in what manner the same is to be performed''*. The Court of Appeal made it clear that these two duties are distinct and have distinct objects, the second of which relates to the consideration to the public in return for the grant of the monopoly and the ability to enjoy *'to the full the benefit of that invention'* (at 265-266). The Court of Appeal dealt with a broad, general description of a method and said, when dealing with the question of sufficiency: *'to say that an invention consists in causing sulphur alone to react on diamidonaphthols is so vague as to 'describe and ascertain' nothing'*; it was common ground that no knowledge previously existed of any reaction between sulphur alone and diamidonaphthols. Their Honours characterised such a description of the invention as a general description which included every kind of reaction between the two compounds, however produced. While they concluded that that could not be said to describe and ascertain the nature of the invention, it also failed to perform the second duty of describing the way in which the

invention was to be performed. In relation to that second duty, the Court of Appeal said (at 266):

> *'[t]hey cannot appeal to common knowledge and say that it would suffice to enable a chemist to carry out the invention, because their own witnesses prove that no knowledge existed at the date of the Patent as to any reaction between sulphur and diamidonaphthols…'*

74 In expanding upon their reasoning (at 269), the Court of Appeal said that:

> *'it is settled law that a patentee must act towards the public uberrima fide, and must give the best information in his power as to how to carry out the invention. He is therefore bound to tell the public all the steps that can advantageously be taken in carrying out the invention. But he is not limited to claiming only the best way of carrying it out'.*

75 That is, a patentee was held to be bound to give the best information in his (or her) power as to how to carry out the invention. This was an element of the required good faith on the part of the patentee and the requirement to give to the public the consideration of knowledge of the best method that corresponds with the obtaining of the benefit of monopoly.

76 In looking to the requirements of best method, Blanco White at [4-502] raises the question of whether a patentee needs to give directions as to techniques of manufacture where the invention claimed is only the finished article: Blanco White (5th ed). This is a reference to *Illinois Tool Works Inc v Autobars Co (Services) Ltd* [1974] RPC 337, on which Servier relies. Blanco White commented at [4-502] that this case meant that it was not clear whether or to what extent there is such an obligation but questioned the outcome in a footnote. Under the separate heading *'Meaning of 'best method''*, there is a statement that the practice is to disclose the most perfect or most complete embodiment known, irrespective of commercial merit. A footnote observes that *'concealment of simplifications known to be commercially desirable should invalidate'.*

77 In *Norton and Gregory Ltd v Jacobs* at 277, the Court of Appeal considered the circumstance where an additional requirement to carry out the invention, which would improve its performance, was not mentioned in the specification, the requirement being one that was known to the patentee at the time that the patent was applied for. The Court of Appeal stated that:

> *'[i]t was therefore incumbent upon him to disclose it in view of Section 25(2)(j) of the Act and his omission to do so is sufficient of itself to invalidate the Patent. Here again, the fact … that a skilled chemist would know or could readily ascertain the necessity*

of leaving the print acid or neutral does not in our opinion afford any justification for omitting so essential a matter from the Specification'.

78 In s 4(3) of the *Patents Act 1949* (UK), the obligations were separately provided for:

> *Every complete specification:*
>
> *(a) shall particularly describe the invention and the method by which it is to be performed;*
>
> *(b) shall disclose the best method of performing the invention which is known to the applicant for which he is entitled to claim protection;*
>
> *(c) shall end with a claim or claims defining the scope of the invention claimed.*

79 It may be accepted that this clear separation of obligations provided the framework for consideration in the cases that followed, but those reasons also demonstrated fidelity to the reasons behind the explicit separate requirements.

80 Accordingly, one sees observations such as those in Blanco White (5th ed) (at [4-502]) that the specification must in the first place contain such instructions as will enable all those to whom the specification is addressed to produce something within each claim *'by following the directions of the specification, without any new inventions or additions of their own'* and without *'prolonged study of matters which presents some initial difficulty'* (citing *No-Fume Limited* at 243 and *Valensi v BRC* [1979] RPC 337 at 377 respectively) and an explanation of the nature of the invention as well as the manner of performing it. These are separate requirements, although the description meeting each obligation is not necessarily separate. The commentary continues to state that the necessary instructions to enable a skilled worker to carry out the invention may or may not suffice to make its nature clear, and that *'somehow or other'* the skilled worker must be told what it is he (or now she) is trying to do to work the invention. Importantly, there is then a further observation that the specification ought to render the working of the invention simple, not merely render it impossible without further invention. Non-disclosure of best method is dealt with separately (at [4-514]) and following, noting that this is not a common objection.

81 *Van Der Lely NV v Ruston's Engineering Company Limited* [1993] RPC 45 contains a discussion about the requirements of s 4(3) of the *Patents Act 1949* (UK). Failure to comply with either of those requirements provided a ground for revocation. Lord Justice Nicholls said

(at 56) that where the claim in issue was to a product, a power harrow, the best method of performing the invention within s 4(3)(b) was the best example of the implement known to the applicant at the relevant time and for which he was entitled to claim protection, where "best" means best in practice and not in theory. The applicant was not required to disclose the best method of using the invention where the method of use was not a feature that was part of the invention claimed. His Lordship said that the distinction between a product and a process was not meaningful because the best way to use the invention would have a significant bearing on what was the best exemplification of the invention: the best way to use the invention would affect the manner in which the implement would be constructed. Further, the patentee was required to disclose, as an example of the implement, the implement with the better method of operation found to have been known to the patentee.

82 The analogy with the present case is apparent.

83 In *Human Genome Sciences Inc. v Eli Lilly & Co* [2013] RPC 22, Sir Robin Jacob, with whom Lewison and Hooper LJJ relevantly agreed, considered the question of "sufficiency" of a claim to an antibody that specifically binds to a polypeptide. The relevant statutory language by this time was Article 83 of the European Patent Convention which provided that a European patent application *'shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'*. Notably, that does not state a requirement for disclosure of the best method. Nevertheless, Kitchin J had summarised the effect of this provision as including such a requirement. His Honour had said that in the case of a product claim, it means *'making or otherwise obtaining a product'*; in a process claim it means *'working the process'*. The claimed invention encompassed many, probably millions, of antibodies, some of which would bind well and others less so, but they could all be made and isolated (at [13]). Sir Robin said (at [16]) that at the level of generality of the patent, all of the antibodies would have a 'use', including uses other than pharmaceutical or diagnostic use, so that each member of the class had potential utility. Sir Robin said (at [23]) that *'[e]ven if the antibodies to be used for the products of claims 18 and 19 do form a narrower class which cannot be ascertained without undue effort that does not mean that the whole class is not enabled'*. However, at [29], Sir Robin turned to discuss an argument based on *Pharmacia v Merck & Co Inc* [2002] RPC 41, where the claim was to a formula consisting of a large number of compounds with no limitation in the claim as to purpose or use. Lord Justice Aldous had said (at [20]) that when the specification was read as a whole, it was clear that the class of compounds was useful for a specific purpose and that was the contribution that merited the

monopoly. The claim was held to be insufficient because it included compounds which did not have the promised activity and was therefore not enabled across its scope even though all the compounds could be made. Sir Robin distinguished *Pharmacia* by saying (at [31]) *'the skilled reader [is not] led to expect any specific activity, only a host of possibilities which may or may not in fact be'*.

84 In the present case, the reader of the Patent has been led to expect characteristics comparable to the stability features set out in the specification. Those features are described in the text and highlighted in tabular form, and said to be the advantage of this invention over perindopril erbumine.

85 Servier relies upon a number of authorities which have dealt with s 40(2)(a) but without any reference to, or consideration of, the words of that section that refer to the best method known to the patentee. For example, in *Lockwood Security*, the High Court endorsed *Kimberly-Clark* and reiterated (at [60]) that, for the purposes of s 40(2)(a), it is not necessary for the inventor to disclose all the alternative means by which the thing or result may be achieved, it is enough to satisfy the *Kimberly-Clark* test.

86 The characterisation of s 40(2)(a) (or its predecessor s 40(1)(a) of the 1952 Act, in the same terms) as consisting of a first 'limb' and a second 'limb', with the patentee required to comply with each limb, has been a feature of a number of cases where the totality of the obligation was considered.

87 Servier submits that there is no scope in the Act, contrary to the consideration of the UK position as set out in Aldous G, Falconer D and Aldous W, *The Law and Practice Relating to Letters Patent for Inventions* (11th ed, Sweet & Maxwell Ltd, 1965) at [228] concerning questions of good faith. Ultimately, Servier submits that allegations of good faith as a ground of revocation disappeared with the 1952 Act where s 100, as does s 138 of the 1990 Act, provided that patents would only be revoked on the specified grounds. While Dr Bodkin (in Bodkin C, *Patent Law in Australia* (2nd ed, Thomson Reuters, 2014) at [5270]) says, citing *Firebelt*, that the obligation to give the best method is to ensure good faith on the part of the patentee, Servier says that this may be the purpose but it is not the best method test.

88 In *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119, Gummow J considered the question of best method as a distinct subject in his Honour's reasons. Justice Gummow traced the history of this requirement as set out in various statutes in Australia and the United

Kingdom. His Honour noted (at [133]) that the requirement to disclose the best method persisted despite legislation omitting particular reference to "best method" and had been a ground of appeal under general law even before legislative provision for the inclusion of a best method. This, his Honour said:

> *'appeared to have been on the footing both that the requirement of making known the best method ensured good faith on the part of the applicant so that grants would not be obtained on false suggestions or representations, and that the patentee should not get the benefit of a monopoly without giving to the public the corresponding consideration for the best method of performing the invention'.*

89 His Honour observed that it was the enactment of s 40 of the 1952 Act that brought with it, in Australia, express reference to the disclosure of the best method, although differently expressed from the requirement in the *Patents Act 1949* (UK). His Honour said:

> *'... section 40 uses the words 'fully describe the invention' and the requirement of 'best method of performing the invention which is known to the applicant' is stated as being included within the obligation to fully describe the invention, rather than being expressed disjunctively', as it was in para (h) of [s 23(1) of the* Patents Act 1949 *(UK)].'*

90 That section's predecessor, s 36 of the 1903 Act, provided:

> *A complete specification must fully describe and ascertain the invention and the manner in which it is to be performed and must end with a distinct statement of the invention claimed.*

91 Justice Gummow noted that in *Welch Perrin & Co Pty Limited v Worrel*, Dixon CJ, Kitto and Windeyer JJ had said that the differences between s 40 of the 1952 Act and s 36 of the 1903 Act (which was modelled on the *Patents, Designs and Trade Marks Act 1883* (UK)) were *'probably of no importance'*, the main requirements being that the specification shall fully describe the invention and the manner in which it is to be performed. Nevertheless, his Honour concluded that there had been an obligation on the part of an applicant to disclose the best method known by the inventor, notwithstanding the differences in the text between the Australian and UK Acts.

92 Servier points out that s 86(1) of the 1903 Act provided that *'[n]o proceeding by way of scire facias'* shall be taken to repeal a patent. Returning to *Rescare*, Servier points to Gummow J's commentary at 133, where his Honour discussed the express provision as to the disclosure of

best method under the UK Act, which was not introduced into British legislation until 1932. However, from Gummow J's explanation, the subsequent removal of those words did not alter the position, concerning the consideration provided by the applicant for a patent and that the making known of a best method ensured good faith and such consideration.

93 In *Eli Lilly & Co v Pfizer Overseas Pharmaceuticals* (2005) 64 IPR 506, Heerey J considered sufficiency and best method under separate headings. His Honour concluded that the ground of insufficiency as determined by the *Kimberly-Clark* test was not made out. Justice Heerey then turned to deal with what he clearly considered a question separate to that of sufficiency and the *Kimberly-Clark* test, namely, the *'best method'*. His Honour addressed a number of questions about the best method: whether it must be identified as the best method known to the patentee, what was the best method known to the patentee, whether the best method was disclosed and, if so, when.

94 The link between best method and the invention is also explained in *Firebelt*, where the Full Court (Spender, Drummond and Mansfield JJ) explained (at [48]) the requirement of the obligation to disclose the best method of performing the invention which, notably, their Honours discussed under the heading 'Non-disclosure of best method of performing the invention':

> *'[this] requirement is to ensure good faith on behalf of the patentee, and to protect the public against the patentee who deliberately keeps to himself something novel and not previously published which he knows of or has found out gives the best results, with a view to getting the benefit of the monopoly without giving to the public the corresponding consideration of knowledge of the best method of performing the invention'.*

95 In *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260 (at 277), the Full Court (Spender, Gummow and Heerey JJ) stated a number of propositions drawn from the authorities, including a citation with approval of the statement by Lord Moulton in *British United Shoe Machinery Co Ltd v A Fussell & Sons Ltd* (1908) 25 RPC 631 (at 650), dealing with the different duties upon the patentee in the filing of a provisional specification and the filing of a complete specification in the context of fair basis:

> *'...there was the danger of confining [the inventor] to a mere outline which gave delimitation, but did not tell the public the best way within those limits of performing his invention. The one duty required him to state his invention in its most general form, and the other duty required him to state it at its best and therefore in a very special form'.*

96 In *Pfizer* (at [327]), the Full Court explained s 40(2)(a) in terms of "two limbs", where the first limb, that the invention be described "fully", imports the requirement of sufficiency of description, the *Kimberly-Clark* test. Accordingly, their Honours considered sufficiency and best method separately. Addressing the first limb, their Honours stated that the requirement of full description of the invention depends for its content in part upon the understanding of the invention, namely *'the embodiment which is described and around which the claims are drawn'* (citing a statement in *AMP v Utilux* at 127, approved in *Kimberly-Clark*). They noted that in *Lockwood Security,* the High Court had held (at [60]) that it is not necessary for the inventor to disclose all alternative means of performing the invention as long as the addressee is enabled to produce something within each claim.

97 Justices French and Lindgren, with whom Crennan J agreed, said at [361] that a historical review of the cases showed that even before the statute expressly required it, a statement of the best method of performance of the invention was required by the courts. Their Honours observed that an express requirement that a complete specification fully describe the invention, including the best method of performing the invention which is known to the applicant, appeared in s 40(1) of the 1952 Act, re-enacted as s 40(2)(a) of the Act. At [374] their Honours placed the best method requirement into context. They said:

> *''[d]isclosure of the best method known to the applicant of performing the invention' (a subjective notion) is a part of describing the invention 'fully'.'*

As their Honours observed, the requirement to disclose the best method known to an applicant safeguards against an applicant's holding back with a view to obtaining the benefit of the patent monopoly without conferring on the public the full consideration for the granting of the monopoly.

98 In *Expo-Net*, Bennett J considered that s 40(2)(a) imposed two requirements: that the description in the specification be sufficient, which her Honour noted had been described as the first limb of the section (sufficient instruction to enable the person of ordinary skills to work the invention without inventive step or undue experimentation) and the further requirement, the second limb, that the specification include the best method of performing the invention known to the inventor. Justice Bennett considered whether or not there had been compliance with the requirement of describing the best method for performing the invention.

99 The claims were to a process. In that circumstance, Bennett J adopted an analysis whereby an applicant for revocation on the ground of failure to disclose the best method must show that (at [16]):

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

100 As explained by Bennett J in *Expo-Net* at [18]:

> *'The Full Court [in* Firebelt*] emphasised (at [48]) that a patentee acting* uberima fide *must give the best information in his or her power on how best to carry out the invention and noted that the inventor is not limited to claiming only the best way of carrying out the invention. The Full Court reiterated that it is part of the consideration for the grant of a statutory monopoly that the inventor give to the public sufficient instruction to work the invention without the need for any new inventions or inventive additions, which of itself obliges the inventor to disclose the best method of performing that invention of which he or she knows. This last requirement has been noted over time (see e.g. Blanco White in* Patents for Inventions*, 4th ed, Stevens, 1974 at para 4-502). As French and Lindgren JJ (with whom Crennan J agreed) observed in* Pfizer Overseas Pharmaceuticals & Ors v Eli Lilly & Co *(2005) 225 ALR 416 at [374], the requirement that an applicant disclose the best method known to him or her of performing the invention safeguards against an applicant's holding back with a view to getting the benefit of a Patent monopoly without conferring on the public the full consideration for the grant of that monopoly.'*

101 Servier relies upon *DSI Australia (Holdings) Pty Limited v Garford Pty Limited* (at [327] and following), where Yates J considered s 40(2)(a) of the Act. In that case the mode of operation of the claimed brake was not explicit on the face of the specification. The claims of the Patent were to an apparatus and the method for manufacturing certain rock bolts. His Honour stated (at [334]) that the patentee's obligations under s 40(2)(a) do not extend to describing or cautioning against something that will not work, saying that *'the patentee's only obligation is captured by the question posed by the High Court'* in *Kimberly-Clark.* From his Honour's reasons, it is apparent that he was considering the sufficiency of the description for the person

of ordinary skill and was not dealing specifically with the question or allegation of a failure to disclose the best method. This is clarified to some extent at [336] where, in considering the challenge for alleged inutility, his Honour noted that the case on invalidity on that ground was the same basis as the case on *'insufficiency'*, noting the distinction as expressed in Blanco White (5th ed) at [4-404]: "insufficiency is when you can't make the thing, inutility is when you can but it doesn't work when you have".

102 Servier submits that the best method requirement is '*a subset of enablement*' and that the only obligation to disclose a method is if it requires something which would not be understood by the skilled addressee. It relies on *AMP v Utilux* at 128-130, where McTiernan J distinguished between patents involving products and patents for methods. Servier says that it is only with the latter that it is necessary to set out the steps.

103 The authorities that have dealt with s 40(2)(a), its precedents and equivalents, must be understood in context. The first, and most important, factor is the nature of the invention being described and claimed. Servier divides this simply into products and processes but that is not sufficient. It is necessary to understand the invention itself in order to appreciate what is required of an inventor by way of disclosure in the specification in order to secure a monopoly from the public. In some cases, the claim to a product will require no description of the method of obtaining it and it can be left to the skilled worker (as in *AMP v Utilux*). In other cases, the product claim, properly understood, will require sufficient directions in order to obtain the monopoly.

104 The Full Court in *Firebelt* observed that the statutory obligation was an obligation to disclose the best method of performing the invention. Their Honours also said (at [53]), referring to the requirement of s 40(2) of the Act (in its totality), that the patentee is required to give the best information in his (or now her) power as to how to carry out **the invention** (emphasis in the original). The Full Court was of the view that the requirement is ordinarily satisfied by including a detailed description of one or more preferred embodiments of the invention and concluded in that case that, by taking account of the rest of the specification together with the figures, an embodiment was depicted of the claimed device.

105 In *Patent Law in Australia* Dr Bodkin says (at [5270]) that the requirement to describe the best method known to the Patentee:

> *'is to supplement the necessity for a full description by requiring the patentee to disclose additional information which, if not available to potential users of the*

invention, could place the patentee in a stronger competitive position even though no patent protection existed [i.e. when the patent ceases to be in force]. It is included to help ensure good faith on behalf of the patentee'.

106 Citing *Firebelt* (at [48]), the author continues (at [5280]) to give the opinion that the patentee must disclose what it, subjectively, perceives to be the best embodiment of the invention known to it at the relevant time, whether or not a different embodiment is later shown to be better. Further, what must be disclosed is the best practical method of carrying out the invention as distinct from the best method in theory (citing *Van Der Lely* at 56). That is, the requirement is to disclose the most effective means of carrying out the invention known to the patentee at the relevant time. The view is also expressed that it appears not to be necessary to describe the best method for making an apparatus or the best method of using an apparatus (citing *Illinois Tool Works* and *Van Der Lely*).

107 While it cannot be held to be definitive or directory, it is worth a passing observation that in the Explanatory Memorandum for the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) (**the Explanatory Memorandum**) at Item 8 concerning s 40 of the Act, it is stated that the existing requirement for a complete specification to include the best method known to the applicant of performing the invention remains unchanged. This was in connection with a proposal, subsequently enacted, to separate the requirements of s 40(2)(a) into two distinct paragraphs:

> *(2) A complete specification must:*
>
> *(a) 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; and*
>
> *(aa) disclose the best method known to the applicant of performing the invention…*

108 From the above authorities the following principles may be gleaned:

- Different policy reasons support the obligation to describe the invention fully and the obligation to provide the best method known to the patentee of performing the invention. The purpose of the former obligation is to circumscribe the monopoly granted to the patentee; the purpose of the latter is to allow the public the full benefit of that invention when the monopoly expires.
- Although a patentee might not be explicitly required to act in good faith, principles of good faith underlie the best method requirement.

- Even where legislation has not included an explicit 'best method' requirement, courts have considered it to be a separate and additional requirement to the obligation to provide a sufficient description of the invention.
- The nature and extent of the disclosure required to satisfy the best method requirement will depend on the nature of the invention itself. Accordingly, a distinction between products and processes that ignores the specific features of the invention claimed is unhelpful.

Conclusion

109 It follows that the courts have recognised the necessity for a patentee to include in the specification not only sufficient instruction to work the invention but also the best method of performing the invention known to him, her or it. This requirement has been developed by the courts over time and has been reflected in statutory provisions, such as in s 40(2)(a). Where the best method question has been addressed by the courts, the separate or additional nature of the requirement has been confirmed, including by the Full Court. We see no reason to depart from this view.

110 It follows that the primary Judge did not err when he came to a similar conclusion at [164], that the sufficiency and best method obligations are *'coordinate requirements'*.

3. The date on which the best method must be disclosed

111 It is not necessary in this case to decide whether the date upon which the patentee must describe the best method known to him, her or it is the date of filing the patent application or the date of grant of the patent. In this case, the 1986 and 1991 methods were known to Servier prior to the date of filing and they were not included in the specification at that date or at the date of grant. However, the parties addressed the question and it is helpful to note discussion of the question in the cases, as it also bears on the question of amendment of the specification.

112 There is much discussion in the authorities of the date at which the specification must disclose the best method known to the patentee.

113 There has been some controversy about the date by which the best method known to the patentee must be disclosed:

- In *Illinois Tool Works*, Graham J concluded that the relevant date was the date of publication of the specification.

- In *Van Der Lely*, Nicholls LJ expressed the view that the requirement was to disclose the best method known to the applicant at the time the complete specification was filed.
- In *Eli Lilly*, Heerey J concluded that the relevant date for assessing best method is, at the earliest, the date of grant and not the date of filing of the application.
- In *Rescare*, Gummow J concluded that the date upon which the best method was to be disclosed was the date of filing of the application.

114 In *Pfizer* (at [375]) the Full Court decided that the date on which the best method known to the applicant is to be identified is conceptually distinct from the date by which the full description must include the disclosure of it. An applicant is required to disclose the best method known to it as at the filing date, as concluded by Gummow J in *Rescare* with respect to the 1952 Act. It follows, their Honours said (at [379]), that the disclosure must be made in a complete specification when it is filed, adding, *'[l]est there be any doubt'*, that s 40(2)(a) requires an applicant for a patent to disclose in the complete specification at the time of filing the best method of performing it known to the applicant at that time.

115 Some of the difficulties with deciding that date were discussed by the Court of Appeal in *Biogen Inc. v Medeva Plc* [1995] RPC 25 (at 100) and following. The Court of Appeal noted that the primary Judge in that case, as had other Judges of note, considered that the date upon which the specification must be sufficient is the date at which it is published. Nevertheless, as Hobhouse LJ explained, this gives rise to *'serious anomalies'*. Accordingly, the Court of Appeal preferred to take the position that the relevant date was the date of filing of the application. One of the reasons given was that an invention which cannot be performed is not a patentable invention and is not capable of industrial application.

116 It seems to be agreed between the parties for the purposes of the appeal that any best method requirement is the best method known to the patentee as at the date of filing, although there is a debate as to whether Servier can amend later in time to include or to add that best method.

Issue 2: Whether the method of making perindopril arginine is necessary for disclosure of the best method of performing the invention

1. Submissions

117 Servier notes that the invention and the subject of the claims is a product. Further, the product is perindopril arginine *per se* and not a particular form of a salt or a particular crystalline form. Servier submits that where a single salt is claimed there is "no room" for the application of a

best method of "performing" the invention. Servier disputes that a method of making a claimed product equates to a method of performing the invention. Rather, Servier submits, the best method requirement is satisfied by the identification of the claimed compound, as in *Eli Lilly* where the claim was for a class of compounds by formula and the body of the specification specifically identified the particular compound that the patentee knew was the best compound within that claim. This was held to be sufficient compliance with s 40(2)(a) and that was not challenged on appeal.

118 Servier also points to decisions such as *Firebelt* (at [46]-[55]) and *Rescare* (at [120]-[132]) for the proposition that where the claim is to the apparatus *per se*, the requirement in s 40(2)(a) is directed to the best form or best embodiment of the invention rather than to the best way of using it. Where the claim is to an apparatus, Servier says that the patentee need not disclose any particular form of the apparatus unless it knew that it was the best form as at the relevant date. Servier submits that this is consistent with English authority such as *Illinois Tool Works* and *Vidal Dyes*, which distinguished between claims to a product and to a process and considered that there is no obligation to disclose the best way of making a claimed product. By contrast, where the claim is to a general process and the patentee knows that within that general process there is a specific process that is best, the patentee must disclose that specific process.

119 Servier points out that there was no pleading or finding in the present case of a particular embodiment of the invention which had superior qualities over other embodiments. Servier also says that it has identified the best embodiment, being perindopril arginine, and submits that this would seem to satisfy the older authorities as to the requirement to provide the best method. In the present case, the precise form of perindopril arginine does not matter for the purposes of the claims.

120 The primary Judge did not find that no method had been disclosed but did find that the term *'classical method of salification'* was wholly inadequate to describe the substantive content for a particular classical method of which the Patentee knew. Apotex rejects classical salification as a disclosure of the method and submits that, as the primary Judge held, as a matter of substance it amounted to no disclosure, because of the multiple variations necessarily included in that broad description. There is no notice of contention seeking to support the outcome on the basis that no method was disclosed.

2. Consideration

121 At the outset, it should be noted that the authorities and principles discussed in relation to the first issue, whether the best method requirement is additional to the sufficiency requirement, must inform the consideration of the second issue, the nature of the disclosure required to describe the best method.

122 The primary Judge found that the 1986 and 1991 methods produced *'crystalline'* perindopril arginine ([149] and [151] and the amendment decision at [4]-[5]). The Patent does not disclose that the product it describes, formed from a *'classical salification'* and used in the pharmaceutical composition as set out in claim 2, was crystalline. It was in the context of the precipitation or crystallisation of the salt as the outcome of a classical method of salification that his Honour referred to the variety of choices, for example, of solvents, duration and temperature within a selected method, which might produce a crystalline salt or a particular salt form, such as a hydrate, that could then be used in a pharmaceutical composition.

123 Section 40(2)(a) requires that the best method of performing the invention be provided. Perform is relevantly defined in the Macquarie Dictionary to include: *'to carry out; execute, do'*; and *'to carry into effect; fulfil'*. The meanings of "perform" in the Shorter Oxford English Dictionary are relevantly *'execute, accomplish, do, (any action, operation or process undertaken or ordered)'* and *'make or construct (an object)'*.

124 The key to understanding the obligation of the patentee is to understand that the section is directed to the method of performance **of the invention**. The monopoly is circumscribed by the claims but the nature of the invention is as described in the whole of the specification. This approach accords with that adopted by Lord Nicholls in *Van Der Lely* and by the Full Court in *Firebelt*.

125 Section 40(2)(a) expressly uses the word "method". Method is relevantly defined in the Macquarie Dictionary as: *'a mode of procedure'* and *'a way of doing something'*.

126 There is no distinction drawn in the language of the statute between a product and a process in providing for the obligation to provide the best method of performing the invention.

127 Servier knew of the 1986 and 1991 methods and the crystalline form obtained from those methods. It knew that this form was suitable for pharmaceutical compositions and that it was in fact used in the stability study referred to in the Patent from which the alleged advantages of the invention are derived.

128 Both parties accept that s 40(2)(a) must be judged through the lens of both claim 1 and claim 2. The use of the product, perindopril arginine, in a pharmaceutical composition was an important aspect of the invention claimed in the Patent. That is made clear in the description in the specification. Indeed it could be said to have been the *'raison d'etre'* of the need to find a more stable product over perindopril erbumine. This was recognised by the primary Judge at [182].

129 It can be accepted that there are cases where the claim is to a product or class of products and the best method requirement is satisfied by a description of the best embodiment known to the patentee at the relevant time. It can also be accepted that there are cases where the claim is to a product and there is no requirement to provide a method of using that product. It is also the case that there is no requirement actually to have carried out the best method and that a prediction will suffice *(New England Biolabs, Inc v Hoffmann-La Roche AG* (2004) 63 IPR 524 at [33]). However, it is necessary to understand the invention itself (*Expo-Net).* As was succinctly stated by Lord Hoffman in *Kirin-Amgen Inc. v Hoechst Marion Roussel Limited* [2005] RPC 9 at [104]:

> *'in order to decide whether the invention has been fully enabled, you first have to decide what the invention is'.*

Lord Hoffman was there addressing the sufficiency requirement, but the observation applies equally to the best method requirement. The nature of the invention will determine what is "best" in the circumstances.

130 The centrality of the invention is also emphasised in the approach that has been adopted in Australia, for example in *Lockwood Security*.

131 This may explain the case which caused some difficulty in the submissions in the appeal as it apparently did to Blanco White (5th ed) at [4-502], *Illinois Tool Works*. There, the complaint alleged failure to describe sufficiently and fairly the method by which the invention was to be performed and a failure to disclose the best method of performing the invention which was known to the patentees and for which they were entitled to claim protection (at 369). The question was whether, where the claim was to an article, the patentee was obliged to describe a method by which such an article could be made; where the claim was to an article having a certain shape, did the requirement to include the best method of performing the invention require disclosure of the method by which it was to be formed? Justice Graham concluded that

there was no obligation to describe how the article was made, accepting the argument that in the case of a claim to an article which is directed to the shape of the article, the method of performance means the production of an article in the shape described irrespective of how it may have in fact been made. The patentee had described the formation of a cup with the wedges shown and the evidence was that it was the conception of the shape that was the invention. That is, the decision can be understood in the context of the nature of the claimed invention and the description that was given in the specification.

132 There are cases where the nature or degree of disclosure for a claimed product are discussed which at first seem to favour Servier's submissions but not when they are properly understood in the context of the nature of the invention being claimed and the consequential disclosure required. An example of such reasoning is that of Sir Robin Jacob in *Human Genome Sciences Inc* above.

133 In the present case, as the primary Judge recognised, the point of the invention was the storage ability of the compound. That storage ability can vary depending on the nature of the salt that is formed, for example, perindopril erbumine did not give satisfactory storage, and can vary with the form of a salt. Accordingly, as his Honour said, the particular salt formation and the methodology to get that salt formation have more importance than might be the case where the claimed invention was a product for which these characteristics were irrelevant.

134 Perindopril arginine is generally a more stable product than perindopril erbumine and the claim is not to a specific form of the arginine salt. If Servier knew of a method that provides a form of the salt with the characteristics exemplified in the Patent, which characteristics provided the stated advantages of the invention over the prior art, it was incumbent on it to provide that method. This would relieve the skilled worker from making the choices within those necessarily made or available in a classical salification. The disclosure of the method known to Servier would not only have relieved the skilled addressee of confronting blind alleys and pitfalls which may not be uncommon in a general sense but also, and importantly, would tell the skilled addressee the methodology to achieve the form that obtains the result which constitutes the invention, that is increased stability and storage length. While claim 1 does not refer to any particular form of perindopril arginine, crystalline or otherwise, if Servier had a method that produced a product that was at least sufficiently crystalline or in a sufficiently good form so that it could be used in the API for the tablets used in the stability study described in the specification, that is precisely what should have been disclosed.

135 Accepting that there was no lack of sufficiency, the mere fact that a complete specification described a method which conveyed sufficient information to a skilled addressee to enable him or her to work the invention does not necessarily satisfy the Patentee's additional obligation to describe the best method. The patentee has an obligation to include aspects of the method of manufacture that are material to the advantages it is claimed the invention brings.

136 In the present circumstances, the inventor, Mr Damien, had not characterised the products of the two methods that he utilised but he did know that those methods created the arginine salt in a useable form and, as a person skilled in the art, he knew that there were many alternatives available from which to choose. As the skilled worker, he knew that the method of classical salification was sensitive to choices such as the choice of solvent. He knew that some were likely not to be as good as others. That is consistent with the expert evidence, although it was not specifically put to Mr Damien.

137 The method of making the perindopril arginine affects the form of that compound and that of the properties of the compound itself, including its stability and usability of formulation. Its making can also involve unnecessary choices and difficulties.

138 The experts' joint report identified some of the vagaries of classical salification, albeit in the context of discussing whether the claimed invention was obvious:

- The suitable solvents or solvent mixture.
- Individually adding one of a range of potential acids or bases (arginine).
- A possible initiation procedure to cause the salt to precipitate out of the solvent e.g. scratching, cooling or the addition of a second solvent to initiate crystallisation.
- If the salt does not precipitate it may be possible to remove the solvent, e.g. by evaporation under reduced pressure or lyophilisation (freeze drying).
- Temperatures.
- Stirring.
- If after evaporation of a solution, the yield is not a solid but a concentrate in the form of a gum, a glass or a foam, that product may be converted to a solid by treatment with an appropriate solvent by trituration. One common laboratory solvent which can often be effective in salt trituration is diethyl ether.

139 Professor Byrn identified such differences as being within the "umbrella" of classical salification, being differences not only in the steps taken but also differences within the steps themselves. There were variables and also the prospect of trial and error within the use of each different variable. Suffice to say that a deal of evidence before the primary Judge concerned the different variables that could be used, the different forms of the salt that could be obtained and the trial and error with respect to the different individual decisions to be taken, all coming within the "umbrella" of a classical salification method.

140 The Patent itself, at page 2, refers to the existence of hydrates which, according to the experts are different forms of the product. The experts agreed that it cannot be assumed that different forms of the compound will have the same properties and that the differences in form could, in some cases, affect the quality or performance of a drug product. The experts agreed with the statement that *'in cases where differences exist which have been shown to affect drug product performance, bioavailability or stability, then the appropriate solid state should be specified'*. Thus, the provision of a method known to provide a crystalline form of perindopril arginine that has the properties described the Patent, including its usefulness in pharmaceutical compositions, would have been of clear benefit to the skilled addressee.

141 The Patent expressly asserts that different forms of perindopril arginine can exist (see page 2 of the specification); and they would be included within claim 1. It is relevant that a crystalline form will be preferable for the purposes of the use as described in the specification, by reason of its properties. Servier relies upon the breadth of claim 1 and the fact that no particular form is specified. However, when the claim is read in the context of the specification as a whole, it is clear that the claimed class of compounds are described as a patentable invention because of their properties, including the use, as set out in claim 2, as a pharmaceutical composition comprising the arginine salt of perindopril and its hydrates. In these circumstances, there is an obligation on the Patentee to provide the best method for producing a form of perindopril arginine that will best fulfil the promises of the invention.

Issue 3: No proven 'best' method

142 The question on the appeal of whether there was a best method known to Servier is directed solely to preparation of the salts of claim 1 and not to the pharmaceutical composition of claim 2. The question is whether, as Servier claims, Apotex had to prove that Servier knew a method that would in fact produce something better than 'a classical method of salification' and that Servier failed to disclose it.

143 Servier says that comparing the information that was common in the 1986 and 1991 methods, each involved the procedure of a standard classical method of salification and that the information omitted from the Patent was:

- a direction to use water as the solvent when mixing perindopril and L-arginine to obtain a perindopril arginine concentrate; and
- a direction to wash the perindopril arginine concentrate with ether to obtain perindopril arginine in a solid form.

144 Servier relies on findings by the primary Judge that:

- Section 40(2)(a) requires a description of the best method known to the Patentee *'that yielded an arginine salt that could be used in a pharmaceutical composition'*.
- Apotex had to prove that Servier knew of a better method than the method disclosed in the Patent.
- Apotex had to prove that the better method was not disclosed in the Patent.
- The Patent does not need to describe what a skilled addressee would know from the description given about details such as analytical agents and commonly used methods.
- Servier had in fact disclosed a method, being a classical method of salification of organic chemistry.
- The 1986 and 1991 methods were *'materially identical'* but there were differences in the quantities of reagents used, water removal techniques, trituration techniques and stirring times.
- Each of the 1986 and 1991 methods produced a form of perindopril arginine that could be used in a pharmaceutical composition.
- Each of the 1986 and 1991 methods was a classical method of salification.
- Each method was a *'simple unoptimised laboratory method'*.

145 Servier's submissions can be summarised as follows:

- The claim is to a product.
- The skilled reader could, with common general knowledge, make a version of the product within the claim.

- Servier concedes that if the process of making the product forms part of the inventive step, then it is necessary for the method to be described. However, the method of making perindopril arginine was not part of the inventive step.
- There was no specific difficulty identified with a method of salification and no pleading or finding to that effect.
- It did not matter what form of perindopril arginine was made according to a classical salification method and any form would provide the benefits of the Patent.
- It could be said that different parameters chosen during the salification process could affect the form of the salt produced and whether it was in a hydrated form or not. However, it would only be if different methods of making the product were shown to have differences that affected the promises of the invention, such as lower stability, that there may have been a further obligation, but that was not the case here.
- There was no evidence of any classical salification method that failed to produce perindopril arginine. There was no evidence that classical salification would fail to produce a product which had a stability or a quality less than the unoptimised 1986 or 1991 methods, or that Servier knew that.
- Servier says that it was not pleaded that it knew that the classical method of salification was inferior to either of the two methods that it did utilise, and the primary Judge did not make such a finding. Rather, Servier says that the basis of the pleading was to the effect that classical salification was not a method at all.
- Servier says that the word *'best'* denotes a comparison. Further, Servier points out that Apotex did not run a case of comparison, and it says that it was for that reason that the amendment to the particulars of validity were allowed and the trial date retained.

146 Servier points out that there was no suggestion in the claims or the body of the specification that the invention and its benefits were limited to any specific form of perindopril arginine. If only one physical form were able to be made from common general knowledge and that form did not deliver a promise of the specification, Servier concedes that the Patentee would not have fulfilled the requirements of the statute. However, Servier points out that there is no claim to inutility and, if one form did not fulfil the promise of the invention, Apotex would have placed utility in issue. Significantly, there was no allegation that any particular form of perindopril arginine would not enjoy the benefits of any promises of the specification, such as stability in a pharmaceutical composition, so the assumption is that there was no want of utility

in any respect (relying on *Sunbeam Corporation v Morphy Richards (Aust) Pty Limited* (1961) 180 CLR 98 (at [111]); *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Limited* (1998) 194 CLR 171 (at [10])).

147 Servier points out that it was not pleaded that there was a deficiency in the classical method of salification or that it would produce a worse product, as recognised by the primary Judge at [177].

148 As the primary Judge found at [159], the evidence was that perindopril arginine was chemically stable as compared to perindopril erbumine and that stability was not affected by perindopril arginine being anhydrous or in any particular hydration state and was not related to a particular crystal form. As far as Servier was concerned, through Mr Damien, the form of the compound did not matter in order to get the benefit of the invention, which is consistent with the broad description of a method of classical salification.

149 Servier submits that on the primary Judge's findings, the skilled addressee would have been able to supply both pieces of information from the properties of arginine as listed in *Martindale: The Extra Pharmacopoeia* (13th ed, 1993), a standard pharmaceutical text. That would have revealed that arginine is very soluble in water, sparingly soluble in alcohol and insoluble in ether. Servier also submits that the skilled addressee would have known that the method in the Patent could involve the use of water, because the skilled addressee would have understood that the Patent was directed generally to perindopril arginine and its hydrates. Servier also points out that while the primary Judge held that different methods could produce a product relevantly worse than the product of the 1986 and 1991 methods, his Honour did not find that this would necessarily occur. It followed that there was no finding that Servier knew that any other method likely to be reasonably employed by the skilled addressee would necessarily produce something relevantly worse than the product of the 1986 and 1991 methods.

150 Apotex pleaded the best method ground by alleging that the invention is not fully described, as it does not describe how to prepare a composition containing perindopril arginine so as to obtain the alleged benefits of the invention. That formulation of the argument was apparently abandoned prior to closing submissions before the primary Judge. Similarly, Apotex did not pursue an allegation that the invention was not fully described, in the sense of lack of sufficiency because the Patent did not describe how to make the perindopril arginine salt, including which forms of perindopril arginine should be made to obtain the alleged benefits of

the invention. Servier submits that it follows that Apotex necessarily accepted that the Patent describes how to make perindopril arginine salts so as to obtain the alleged benefits of the invention. To clarify this, Servier said that, in not pursuing an argument of insufficiency, Apotex accepted that at least one embodiment was sufficiently described.

151 Servier also submits that Apotex did not plead, and the primary Judge did not find, that following the method disclosed in the Patent would produce something relevantly worse than the 1986 and 1991 methods. Servier submits, but Apotex denies, that Apotex had to prove, but did not prove, as a matter of fact that the classical salification method described in the complete specification was worse and that this was known to Servier. There was no finding or pleading that any variant of the classical method of salification would not produce an equivalent product to that produced by the 1986 and 1991 methods. Accordingly, speculation that choices could be made to produce a worse product are irrelevant and do not discharge the relevant onus of establishing that either of the 1986 and 1991 methods is in fact a better method (*Expo-Net* at [16]).

152 Servier submits that the primary Judge erred in rejecting what it says was an essential requirement: that Apotex had to prove that the skilled addressee, using another classical method of salification, would have achieved or did achieve a worse result than did Servier in the methods known to it and not disclosed. Servier also adopts the argument that if the highest that the findings of fact could establish was that changing parameters **could** affect the result, then Apotex would have failed on the balance of probabilities to establish that the best method had not been disclosed.

153 Servier also submits that Apotex has failed to establish the matters identified in *Expo-Net* (at [16]), being a summary of what a party seeking revocation on the grounds of failure to satisfy the best method requirement must establish. Those matters are set out above at [99]. Servier also says that there is no identification of a step that would fail and the step that would be taken to overcome that failure, such as trying another solvent. The primary Judge did not, Servier says, actually make a finding that there was trial and error involved. His Honour said that it was potentially the case.

154 Servier submits that the fact that the skilled addressee employing a classical method of salification would need to make certain choices such as a solvent is not relevant. Servier points out that every patent description of a method leaves out details and submits that unless it is shown that a different choice of the details of the method would have produced a materially

different result, the mere fact of the choice cannot render one method better than the other in circumstances where the *Kimberly-Clark* test is otherwise satisfied.

155 Servier also emphasises that there is no version of the product which is encompassed in the claims that does not satisfy the promises of the invention. That is, whatever form of perindopril arginine that is made, the presumption is that it enjoys the benefits stated in the specification, as noted above. As to other matters that were not demonstrated, Servier points out that there was no evidence, nor did the primary Judge make a finding, that there was a difficulty in actually making perindopril arginine.

156 On the one hand, telling the skilled reader to apply a classical method of salification could be said to be simply telling the skilled reader make a salt. Servier equates "classical" with 'standard'. The evidence was that this involves more or less equal molar parts in the solution, extracting out of a solution and, if the result is not a powder, trituration. Servier's explanation is that by stating that the method was a classical method of salification, the skilled reader is informed *'that there's no trick to it'*. Otherwise, Servier says, even that direction was not necessary for sufficiency purposes.

157 Section 40(2)(a) refers to the "best method" and does not invite a comparison. Apotex relies on the primary Judge's comments (at [179]), where his Honour accepted the expert evidence that the mere reference to a utilisation of a classical method of salification was wholly inadequate to describe the best method or any substantive content of any particular classical method of which the Patentee knew of performing the invention. That is, the primary Judge not only effectively held that there was no method, he also upheld the alternative argument, that the method as described had no substantive content or was inadequate to give any substantive content.

158 Apotex's position at trial, which necessarily was the one considered by the primary Judge, was that the reference to *'a classical salification'* in the Patent disclosed no method at all. Apotex submits that whether the Patent is characterised as disclosing no method or one that is lacking *'any substantive content of any particular… method'*, as stated by the primary Judge at [179], makes no difference to the substance of Apotex's argument.

159 Apotex submits that, unlike *Firebelt* and *Illinois Tool Works*, the bare description in this case does not permit the skilled reader to follow a routine process of deduction from the description, because it leaves open too many variables. Apotex submits that the primary Judge was correct

in rejecting Servier's argument that Apotex had to prove that the skilled addressee, using another classical method of salification, would have achieved or did achieve a worse result than in the 1986 or 1991 salifications.

160 Servier summarises this part of its case as follows:

- Classical salification is a method, and was found by the primary Judge to be so.
- All of the experts were able to say what they understood classical salification to involve.
- That description is a short hand expression understandable by the skilled addressee to use equimolar amounts or thereabouts of suitable solvents, extract the result of that if necessary, triturate and dissolve the powder by using other suitable solvents.
- The experts knew the range of suitable solvents.
- It does not matter whether the matrix of classical salification contained a number of specific methods, the fact is that a skilled addressee understands what it refers to.
- The obligation is therefore on Apotex to show that the method known to Servier either did not work or did not work to produce a form which resulted in the stability described.
- Apotex must also prove that the disclosed method was worse than the 1986 or 1991 method.
- Servier also submits that there was no evidence to support a finding that an expert engaged in carrying out a classical method of salification would have encountered error in the sense of a conclusion there would be *'trial and error'*. There is no evidence of actual failure.
- The skilled reader knew from the specification that perindopril arginine could be formed.

161 Servier submits that there has to be knowledge in the company as to why the method given was not the best method. Servier points out that Mr Damien was never asked whether he knew that "classical salification" was not as good a method as one that he knew.

1. The evidence

162 The scientific evidence on which Servier relies as to the making of organic salts includes:

- It is a straightforward part of chemistry.

- If a crystalline salt is formed, the salt is typically insoluble in the solvent and will precipitate out. The salt can be filtered off. If the salt does not precipitate, the solvent may be removed by evaporation.
- As supported by Professor Byrn, once it is known from the Patent that a salt has formed and that it is a solid, the choices available in a classical salification are much simpler.
- The experts addressed choices of solvents and gave reasons why they would be directed to use a limited number of solvents or solvent classes.
- Apotex's witness, Associate Professor Perkins, agreed that the making of salts of perindopril using a range of acids and bases is a straightforward procedure that can be done in a laboratory.
- The many variables can be manipulated to seek to obtain a crystalline product. Such manipulation is taught at undergraduate level.
- Some salts can present challenges but the process can be straightforward.
- There was no evidence that perindopril arginine presented a particular challenge.
- Perindopril arginine is characterised by a lack of volatility, which is not related to a particular crystal form or to the extent of hydration of the salt although different solvents might give rise to different solid forms.
- Classical salification tends to make the most stable form of a compound.
- Irrespective of whether there are different crystal forms of a salt, it is still the salt.
- Professor Evans' evidence was that while a salt could come in different forms, if they are produced by a classical salification, it was unlikely that multiple polymorphs would result which would possibly but not necessarily differ in terms of stability.
- While it was accepted by Professor Byrn that a classical salification can frequently result in a gum or a foam, trituration was then part of the process.
- Trituration was part of the process conducted by Servier in the 1986 and 1991 methods.

163 Servier accepted that Professor Byrn did say that there **could** be differences in stability between perindopril arginine monohydrate and perindopril arginine dihydrate by using different solvents but whether or not there is a difference can only be tested by analysis. Professor Byrn's evidence was to the effect that the phrase *'classical method of salification'* suggested to him that a choice of a specific solvent and conditions were not critical. He also said that while making an isolable solid is not always easy, it can be easy and the fact that the Patent

states that the arginine salt can be obtained by conventional means indicated to him that it comes into the latter category. Further, when it is known that a salt can be made by conventional methods, Professor Byrn says that he would expect, and would have considered, that the person skilled in the art would also expect to be able to make the salt without difficulty.

164 That position was not necessarily commonly held. Dr Morella, for example, said that he could not have predicted the lack of difficulty in obtaining the arginine salt, even if the Patent stated that there was no difficulty in obtaining it by classical methods.

165 In the joint expert report, the experts agreed on the answer to the question: "how would I go about making perindopril arginine?" as follows:

> *A typical salt preparation would involve taking a solution of perindopril in an appropriate solvent or solvent mixture and mixing it with a solution of one molar equivalent of arginine. This may or may not result in direct crystallisation or precipitation of perindopril arginine. If crystallisation or precipitation of perindopril arginine occurs, the solid salt may be collected by filtration. Alternatively, if crystallisation or precipitation does not occur, the solution may be evaporated to low volume or to dryness. This may yield a solid, or it may yield a concentrate in the form of a gum, a "glass", or a "foam". This concentrate may be converted to a solid by treatment with an appropriate solvent, a process called "trituration". One of the common laboratory solvents which can often be effective in salt triturations is diethyl ether. However, use of a different solvent might give a different solid form (polymorph or hydrate or solvate). Indeed, there are many parameters (including solvent) which could influence the solid form of perindopril arginine which we might obtain from a classical salt preparation, and the approach used would depend on the context, i.e. "salt screen" versus "improving/optimising solid form".*

166 As to the next question, "would I have any difficulty in making perindopril arginine?", the response was:

> *Knowing that perindopril arginine can be formed (as per patent AU 700) we would expect to be able to make the compound. There were some differences within the group relating to our understanding of the term 'difficulty'.*

167 Apotex points to evidence that it says is relevant, including:

- The 1991 method was the method used to make the tablets that were reported in the Patent to demonstrate the superior stability of perindopril arginine over perindopril erbumine.
- The evidence did not show that every possible salification will end at the same place.

- The solvent chosen by Servier for the 1991 method was not necessarily the solvent of choice for the skilled reader and led to the use of lyophilisation. Lyophilisation was used for the 1991 method.
- A different solvent was used in the 1991 method for the trituration step. Trituration was used in both the 1986 and 1991 methods.
- Servier had to carry out steps of lyophilisation and trituration with a different solvent, suggesting that the simplest form of salification was not, or would not be, successful.
- Professor Byrn explained that there are at least five methods of crystallisation which involve potentially many different variables, each of which can affect the results.
- Dr Spargo agreed that changes in formulation in the salt formation process or the tablets could produce different results, as well as involving considerations of time and money.
- Servier adduced evidence from Dr Spargo to the effect that whether or not a process produced a different polymorph or even a different hydrate can only be tested by experiment and analysis. The same applies to testing for stability and otherwise it is a matter of speculation.

168 Professor Byrn also gave evidence that if two people employed what they regard as classical salification to produce perindopril arginine and used slightly different methods within that classification, the form of the resulting compound in terms of polymorphs and hydrates and the different properties in terms of stability could only be known after testing. However, Professor Byrn added that while one cannot generalise, usually there is one most stable form of a compound and the classical salification would tend to make that form.

169 Further relevant evidence included:

- The experts agreed that there are many different variations on the process of classical salification.
- The knowledge that there is a salt and that it is an arginine salt reduces the choice of parameters. However, Professor Byrn agreed that with different solvents and different cooling conditions, the result might be different polymorphs of perindopril arginine.
- The type of solvent or solvents and other ingredients in the salification process could produce a range of outcomes of perindopril arginine in a polymorph form or a hydrate form, or different species of those forms.

- Professor Byrn said that what he drew from the Patent was that whatever form of classical salification was used, the skilled worker should be able to produce some form of perindopril arginine that may be useable, whether or not it may be granted a regulated pharmaceutical use.
- Professor Evans added that in order to get approval from regulators, polymorphism was relevant, so that from the regulatory viewpoint examining a new submission for a drug that is a solid, the regulators may or may not be concerned with polymorphism.
- Professor Evans said that although the Patent says that it is covering perindopril arginine and its hydrates, as there is a possibility that the drug could be present in several hydrated forms, that form would potentially depend on the particular method or ingredients used for a classical salification.
- Dr Morella agreed and added that, to him, the Patent gives no indication that there is a difference in the form of perindopril arginine. That is, it could be amorphous, or crystalline, or one of the hydrates.
- However, Dr Spargo stated that it is possible that the differences in solubility and bioavailability between different polymorphs and between those and the different hydrates or, indeed polymorphs of hydrates, may or may not be significant.
- There was also evidence from Associate Professor Perkins that variables can impact on whether a solid form is obtained or not.
- From the joint report, it is apparent that the steps of lyophilisation or trituration were used by Servier in order to obtain the desired result. At the least, it could be said, that involved further steps in the process and therefore more time in preparation.

170 Further, the experts agreed that a crystalline substance is preferable to a non-crystalline form. The experts identified a number of variables within the range of classical methods of salification, including the method of crystallisation used, as well as the choice of solvent and whether to conduct a trituration step. These variables could result in either not obtaining a crystallised form at all or obtaining a different form of perindopril arginine.

2. Consideration

171 From the evidence, including in the joint report and in the concurrent evidence, it is apparent that the findings made by the primary Judge were open to him as to the effect of different

parameters on the form of the product obtained and as to the fact that there may be different approaches from different skilled readers as to what constitutes *'a classical salification'*.

172 The primary Judge did not find, and there was no evidence, that a different method would actually yield a result that was not as good as the 1986 and 1991 methods, but that does not relieve Servier of its obligation to identify the best method known to it. This is not a case where two methods of the same type, both known to the patentee, are to be compared and where it is to be determined, as a factual matter, which is better than the other. In this case, the comparison is between an "umbrella" method, or a general methodology, and a specific method which was sure to provide the benefits of the invention. Apotex did not submit that on the balance of probabilities it established that the skilled worker following a method of classical salification would not get as good a result as that achieved by the Patentee. Rather, it submitted that there was uncertainty as to whether the result would be as good as the one achieved by Servier. Apotex did not put to the primary Judge, nor does it put on appeal, that there could be a positive finding that there would not be as good a result. To the extent that the primary Judge seems to have suggested that Mr Damien gave that evidence, he did not. Rather, it was the evidence of the experts that led to the conclusion that some salts would be likely not as good as others. For example, Professor Byrn accepted that there are many potential choices available that may not lead to a successful preparation of the crystalline arginine salt or hydrate. As the primary Judge said at [187]: *'[b]y omitting a sufficient description of the or one successful method it had employed, the Patentee failed to describe in the complete specification the best method known to it of performing the invention. Hence it did not satisfy one of the essential requirements of s 40(2)(a)'*.

173 Servier's disclosure was of a class of methods. The fact that the claimed compounds were salts means that a salification step or process was required. The disclosure of the 1986 or 1991 methods would have saved the skilled addressee the possible dead ends and false starts that would otherwise have been risked in attempting to make the salt. It would have disclosed certainty of method rather than leaving the skilled addressee at risk of failure and of choosing from all of the parameters that may be used in classical salification.

174 There was no challenge to the primary Judge's findings that there were difficulties and uncertainties involved in carrying out a classical salification to a successful end point with a particular product. Nevertheless, in responding to the argument that the evidence did demonstrate that, on the balance of probabilities, other methods would have involved more trial

and error and therefore more time and expense than the two methods of which Servier knew, Servier says that there was no finding to that effect and that, to the extent that there is an inference, there was no evidence to support it. Servier says that to demonstrate an error (that would lead to a process of trial and error), there must be a failure. Servier argues that a revoker must demonstrate that a method known to the patentee was the best method in comparison with any method identified in the Patent. It follows from this argument that a Patentee does not have to disclose the method used and does not fail to comply with the requirement to provide the best method unless the patentee has actually examined a way of making the product and shown that one way of doing it did not work, or worked less well. That is, there would be no requirement to disclose the best method unless the patentee had actually taken that course.

175 Servier also points out that the specification identified a classical method of salification as a method that worked and that there is no allegation by way of false suggestion or otherwise that that assertion was untrue. However, it follows from Servier's submissions that a Patentee may choose to hold back a specific method that has worked and put in a general method, and that that would constitute sufficient compliance with the requirements of s 40(2)(a) of the Act unless it can later be shown that the patentee had tried another method within that general method, which did not work.

176 Servier's response is that in the present case it employed two versions of a method of classical salification and that there was no obligation actually to employ the best method identified, as it is sufficient to make a prediction unless it knew of something to the contrary. On this approach, the two implementations carried out by Servier could be seen as a test of the method that has been disclosed and that it made a justifiable and reasonable prediction as to the workability of the general method. That is, Servier took two specific examples and inferred that the general would work, thus giving the skilled addressee information as to what the Patentee believed was the best method.

177 Servier argues that a method was disclosed in the specification because Apotex did not contend that the claimed invention lacked utility. That does not follow. The claims were to a product. Apotex's concession means that the form of the claimed invention fulfils the promises of the invention, that is, that the products provide the claimed stability. This does not mean that the specification has disclosed a method of obtaining that range of products. That submission was probably advanced to counter Apotex's assertion that no method has been disclosed and that the description of 'a classical method of salification' does not amount to a method. The primary

Judge rejected that submission, correctly. To the skilled reader, that represented the description of what could be described as well understood methodology which encompassed a class of available methods utilising different parameters.

178 In our view, Servier has not demonstrated error in the primary Judge's conclusion that, in describing only the general method of classical salification rather than a specific method, such as the known 1986 and 1991 method, which would have provided the information to the skilled reader of a method for obtaining a form of perindopril arginine which met the characteristics of the claimed invention, Servier failed to describe the best method known to it of performing the invention.

The admissibility of MFI 2

179 As part of its notice of contention as to the best method decision, Apotex takes issue with the decision of the primary Judge not to admit a document referred to as MFI 2, which later became part of MFI 10. That document is a letter from Servier's solicitors to the Commissioner of Patents dated 3 September 2010. In MFI 2 the solicitors described the problems that Servier found when the arginine salt was obtained in a non-crystallised form. This result was said to have *'several problems'* including:

- Low filterability.
- Solvent retention.
- Bad processibility of the powder e.g. difficulties during grinding; caking.
- Hygroscopicity, potentially leading to the formation of undesired by-products.
- Lower term chemical stability of the active principal.

180 The letter continues:

> *'[t]he present invention is the result of extensive research carried out by the Applicant, which ultimately succeeded in obtaining the α-crystalline form of the perindopril arginine salt. The majority of the experiments carried out by the applicant led to highly viscous, gelatinous product which was difficult to process'.*

181 The letter continued to provide tabular information which was said to show that the addition of only one organic solvent to an aqueous solution of perindopril and arginine does not lead to a well crystallised solid but that, in contrast, the use of a polar solvent and an apolar solvent 'according to the process of the present invention' allows the α-crystallised form of the L-

arginine salt to be obtained. It is to be noted that there was no reference to trituration and that MFI 2 was written in response to an examiner's report dated 25 March 2010 with respect to Australian Patent Application No. 20072204354 entitled 'alpha crystalline form of the arginine salt of perindopril, process for preparing it, and pharmaceutical compositions comprising it', which was filed after the Patent.

182 Apotex sought to tender MFI 2 to counter Servier's argument that the onus was on Apotex to establish a worse result upon the use of classical salification. Apotex sought to tender the letter as an admission by Servier and then to ask some questions of the experts. Apotex says that MFI 2 was to be used in cross-examination of the experts in relation to that topic. It was not earlier provided to the experts, nor the subject of proposed evidence. Apotex says that until Servier opened with the argument that Apotex had the obligation to prove that fact, namely a worse result with classical salification, Apotex's position was that there was no method disclosed, and so there was no need to prove that any other method produced a worse result.

183 The primary Judge rejected Servier's argument that Apotex had to prove a worse result in order to establish a contravention of s 40(2)(a) and rejected the proposed tender as irrelevant. Part of the reason for rejection of the tender was that Apotex had not pleaded that a worse result would be achieved and further that MFI 2 was written after the filing date of the application for the Patent. Apotex submits that if contrary to its submissions, it was required to negative Servier's argument that no worse result would be obtained by other classical methods of salification, the primary Judge erred in rejecting MFI 2.

184 Servier submits that Apotex is not presently entitled to challenge the primary Judge's rejection of MFI 2 because:

- The point was not raised in Apotex's notice of contention or in its notice of cross appeal.
- Apotex has not identified the nature of its challenge in circumstances where the tender was rejected at trial on a number of grounds.
- Apotex cannot rely on MFI 2 with respect to an assertion that the product of the 1986 and 1991 methods was crystalline, as Apotex never sought to tender MFI 2 to prove this fact and did not raise this factual contention below. Thus, neither the experts nor the trial Judge *'squarely addressed it'*.
- There was no evidence that Servier had investigated the precise form of perindopril arginine produced by the 1986 and 1991 methods by the date of filing of the Patent and

therefore MFI 2 could not establish that it knew of or believed that there was any particular advantage in perindopril arginine taking a particular form.

- The evidence of the inventor, Mr Damien, was that he believed that the chemical stability of perindopril arginine did not depend on the form that it took.
- The primary Judge referred to the notebooks recording the 1986 and 1991 methods and thereby referred to the product as *'crystalline substance'* but his Honour also noted that there was no evidence that it had been characterised as having a crystal structure, which would itself have necessitated separate testing.
- There was no evidence that the methodology set out in the MFI 2 was a method of classical salification.
- Accepting that MFI 2 did not mention trituration, the process in MFI 2 was potentially useful on industrial application and the evidence was that trituration would not be used in such a process.
- Correspondence as to another patent dealing with what might be useful on an industrial application or a wider application would not have informed the present case but would have involved the need to address matters by way of further evidence which, if MFI 2 had been admitted, Servier would not have had the opportunity to adduce.

185 To the extent that Apotex is advancing the contention that Servier knew that the product resulting from the 1986 and 1991 methods was *'crystalline'* in the sense of being a solid precipitated product, this was not argued below. It did not arise in Apotex's pleading and was not the subject of expert evidence. MFI 2 does not establish that as at the date of filing of the application for the patent that the inventor considered a particular form of the compound rather than its benefits.

186 The primary Judge rejected the tender for a number of reasons, in summary:

- Apotex's pleaded case was confined to an allegation that the patent contained no method, not that a worse result could be achieved.
- MFI 2 was from 2010 and could not shed light upon what Servier knew when the application for the patent was filed in 2003.
- Apotex should have made MFI 2 available for the expert witnesses.
- The contents of MFI 2 should have formed part of Apotex's pleaded case either in chief or in reply.

187 The primary Judge seemed to have accepted Servier's submissions as to the difficulties that arose because Apotex's allegation of failure to disclose best method only arose late in the course of the proceeding and was included in the grounds of invalidity by amendment. In support of its application to amend the particulars of invalidity Apotex said that the only evidence necessary for determination of the best method question was the matters disclosed in the specification itself. This was in the context where Apotex's position was that no method had been disclosed in the specification.

188 Apotex's case is that MFI 2 should have been admitted as it only became relevant after Servier's opening. Apotex says that the experts were capable of dealing with it in a fairly simple compass and that it was only a fall-back position for Apotex, which maintained that there is no legal requirement for it to establish that there was in fact a method that gave rise to a worse result but submits that, if it is wrong in law, then MFI 2 should have been admitted, as it would have answered Servier's argument. Apotex also says that it sought to use MFI 2 to show that a classical method of salification could in fact produce something worse, and that the laws of chemistry did not change between 2002 and the date of the proposed tender.

189 The reasons given by the primary Judge for rejecting the tender of MFI 2 are persuasive, as are Servier's submissions as to the relevance of the document and as to the consequences of the timing of Apotex's amendment to plead the best method issue and the timing of the tender in the context of the expert evidence. Apotex has not established that the primary Judge erred in this regard.

False suggestion

190 In this appeal, by notice of contention Apotex relies on two asserted false suggestions, characterised as the 'temperature representation' and the 'shelf-life representation'.

191 In light of our conclusions in respect of s 40(2)(a), it is unnecessary to consider these grounds.

The cross-appeal in respect of the declaration decision

192 Although the primary Judge's decision to make a declaration was the subject of a cross-appeal by Apotex in the proceedings with respect to the best method issue, its significance in the context of these proceedings relates to both the amendment and costs decisions. Accordingly, it is dealt with at [273] to [276] and [316] below.

THE APPEAL IN RESPECT OF THE AMENDMENT DECISION

193 By a further amended interlocutory application filed on 8 October 2014, after the delivery of the best method decision, Servier sought to amend the Patent pursuant to s 105(1) of the Act to include methods of making perindopril arginine.

194 Section 105 of the Act provides:

> *105 Amendments directed by court*
>
> *(1) In any relevant proceedings in relation to a patent, the court may, on the application of the patentee, by order direct the amendment of the patent, the patent request or the complete specification in the manner specified in the order.*
>
> *(2) An order may be made subject to such terms (if any) as to costs, advertisements or otherwise, as the court thinks fit.*
>
> *(3) The patentee must give notice of an application for an order to the Commissioner, who is entitled to appear and be heard, and must appear if the court directs.*
>
> *(4) A court is not to direct an amendment that is not allowable under section 102.*
>
> *(5) The patentee must file a copy of an order within the prescribed period.*
>
> *(6) On the filing of a copy of an order, the patent, patent request or complete specification is to be taken to have been amended in the manner specified in the order.*

195 The particulars of the amendments to the Patent were are as follows:

> *After page 3, insert new page 3A with the following text:*
>
> *The arginine salt has been made in the following manner. 12 g (32.56 mmol) of perindopril (free form) and 5.67 g (32.56 mmol) of L arginine were mixed and then dissolved in 150 ml of permuted water. The resulting mixture was filtered on a sintered filter to eliminate insoluble particles. The filtrated solution was then lyophilised (free dried). The residue was taken up again in 150 cc of anhydrous ethyl ether, stirred for two hours and passed through a sintered filter again, before being dried in a desiccator. This resulted in a white crystalline product weighing 16.58gm.*
>
> *The arginine salt has also been made in the following manner. 16.268 g (44.15 mmol) of free form perindopril was mixed with 7.306 g (41.94 mmol) of L arginine and 50 ml of permuted water. Those three ingredients were mixed in a 100 ml spherical flask, resulting in a semi-limpid solution. This was stirred for 15-20 minutes and evaporated until dry. The residue was retaken in a trituration using 150 ml of anhydrous ether. The solution was stirred overnight. Then the product was filtered under a vacuum, washed again with anhydrous ether and dried again in a desiccator under another vacuum. This produced 21.29 gm of white crystalline substance, being perindopril arginine.*

> *The arginine salt may also be made in the following manner. Load 15 kg of perindopril tert-butylamine and 32.52 kg of toluene in a reactor. Add, under stirring, 8.473 kg (33.96 mol HCl) of a prepared solution of concentrated hydrochloric acid and 9 kg of permuted water. Separate the organic phase and then extract twice the aqueous phase with 13 kg of toluene each time. Load, under stirring, the combined organic phases in a further reactor containing a prepared aqueous solution of 5.325 kg of L arginine. Separate the aqueous phase. Wash the organic phase with 7.5 kg of permuted water and filter the combined aqueous phases. Cool the solution to about 3°C, and add 385.14 kg of filtered dimethylsulfoxide to the combined aqueous phases without allowing the temperature of the reaction mass to exceed 16°C. Collect the precipitated solid on a closed filter and wash the cake twice with 71.5 kg of acetone each time and then once with 69.3 kg of methyl cyclohexane. Dry the product at 65°C for at least 36 hours. This produces approximately 13.481 kg of dried perindopril arginine.*

196 It can be seen that the proposed amendments to page 3A were to add a detailed method for the making of the arginine salt. As stated in the amended statement of grounds in support of the proposed amendment to page 3A, it *'describes two methods for making the arginine salt of perindopril'*. That amendment was opposed by Apotex and by Actavis, which responded to the advertisement of the proposed amendments.

197 Servier also proposed the deletion of claims 8 to 11, which Apotex did not oppose.

198 Apotex accepts that the amendments sought are not *'not allowable'* under s 102 so that s 105(4) does not apply. Apotex accepts that Servier has satisfied, or will satisfy, the requirements of s 105(3) of the Act and r 34.41 of the *Federal Court Rules*. It also accepts that Servier has complied with the formal requirements for amendment under s 105 of the Act.

199 The issues said to arise in the appeal from the primary Judge's decision to refuse Servier's application to amend the Patent are:

- Whether the primary Judge erred in refusing Servier's application to amend the Patent by reason of either a letter written by its patent attorney (**the Harris Letter**) referring to the inclusion of a method of manufacture of perindopril arginine in the specification or Servier's response to that letter.
- Whether it is possible to cure a failure to comply with the best method requirement by amendment under s 105 after the date of filing of the patent application and after the grant of the Patent.
- Whether Servier's delay in applying for amendment after the best method decision was unreasonable.

- The relevance of a further method carried out by Servier in 2002 (**the 2002 method**) and whether Apotex and/or Actavis were estopped from relying on that method in resisting the amendment sought.

200 If the first of these issues is determined in Apotex's favour, the remaining issues, which were found by the primary Judge not to be relevant to the exercise of the discretion to permit amendment, concern additional matters said by Apotex to weigh against permitting amendment and to support the primary Judge's decision.

The decision of the primary Judge

201 The primary Judge characterised the content of the amendments that were before him. First, originally, Servier applied to amend the complete specification to include a description of each of the 1986 and 1991 methods. Subsequently, Servier added to those proposed amendments, first, to state that each of the 1986 and 1991 methods had produced a white crystalline substance and, secondly, to describe an industrial scale method that it had used in late 2002 to manufacture perindopril arginine tablets (i.e. the 2002 method).

202 The primary Judge identified (at [9]) four issues arising from the amendment application which required resolution:

(1) what is the proper construction of s 105 of the Act and the nature and scope of the discretion that it confers on the Court to grant an amendment (**the construction issue**)?

(2) was the amendment application futile because it was not possible to amend a complete specification after a patent has been granted (**the futility issue**)?

(3) what was Servier's knowledge and state of mind in relation to the requirement to disclose the best method known to it of performing the invention during the period up to the grant of the patent (**the Servier's knowledge issue**)?

(4) should the amendment be granted (**the discretion issue**)?

203 The factual basis for Servier's amendment rested upon the evidence of Dr Jaguelin, the patent director for Servier since September 2001. His Honour noted that there was no serious challenge to Dr Jaguelin's credibility and, in any event, his Honour found her evidence to be generally honest and reliable (at [29]). Dr Jaguelin's evidence was that she had believed that the Patent had satisfied the best method requirement and that there was no need to amend it. She first contemplated whether to apply to amend the Patent only after delivery of the best method decision. The amendment proposed initially, to add the description to the 1986 and

1991 methods, was to overcome the findings with respect to s 40(2)(a) and the finding that claims 8 to 11 had no basis, as there were no examples given in the complete specification.

204 His Honour noted Dr Jaguelin's reasons for her belief that it was not necessary to disclose the means of making the claimed salts in the Patent application as filed.

205 Dr Jaguelin's evidence also recorded the steps taken by Servier in 2002 in preparation of the commercialisation of perindopril arginine, including the development of the industrial process of salification and the development of several crystalline forms of perindopril arginine. Dr Jaguelin said that she was unaware of those matters at the time before the filing of the complete specification. Dr Jaguelin also explained that her view was that there was no need to include a specific method, because she considered that it was sufficient to state that the product was made according to classical chemistry processes which, in her view, were simple processes. In particular, Dr Jaguelin had said that Servier had not tried to withhold or hide anything in the way in which the complete specification was worded. She also relied upon her knowledge of the requirements for patents in other jurisdictions and considered that the Australian Patent, which is the same as the US Patent, was sufficient to comply with the best method requirement which, in her experience, was not generally a requirement in other jurisdictions.

206 The primary Judge recorded (at [44]) that Dr Jaguelin accepted that Mr Damien's notes of the use of the 1991 method recorded that it produced a form of the arginine salt which was a white crystallised product and she accepted that, when making tablets, the crystalline or powdery form of the salt was much less difficult to use than a glassy or viscous one. She reiterated, however, that, in her view, patents claiming a salt never describe the method of making that salt and denied that the decision not to include a method that produced a crystalline product was in any way a deliberate decision to leave open the possibility of subsequently filing patents claiming methods or crystalline forms of the salt. The primary Judge accepted her evidence.

207 The primary Judge also recorded correspondence between Servier's patent attorney and Dr Jaguelin. In particular, on 3 September 2004, Servier's patent attorney, Ms Harris, forwarded to Dr Jaguelin a copy of the first examiner's report. Ms Harris wrote the Harris letter as a covering letter in which she referred specifically to voluntary amendments to the specification. Ms Harris made a recommendation with respect to claims 8, 10 and 11, being that further examples should be added (if possible) and, in addition, she recommended the inclusion of a method for the manufacture of the arginine salt of perindopril, even if the manufacturing method was well known in the art, so as to satisfy the written description requirements. Dr

Jaguelin's reply of 20 December 2004, relevantly, enclosed part of a bioequivalence study but expressed hesitation about giving it to the Patent Office, as it was confidential. She also expressed the view that there was no need to add more detail to the description of a classical method of salification of organic chemistry and added *'we will see later'*. She gave evidence, which was not challenged, that she meant that she would wait for the examiner's comments. There were no further comments from the examiner.

208 The primary Judge noted that the 1986 and 1991 methods offered a proof of concept that it was possible to make a useful crystalline substance comprising perindopril arginine that could be used in tablet production, but that both of these laboratory methods were not suitable for use on an industrial production scale. The 2002 method was to achieve that purpose. By 27 February 2003, Servier had manufactured a total of about 23.1 million tablet doses using perindopril arginine produced by that method. In about May 2003, Servier received the results of the stability studies of perindopril arginine tablets made using the 2002 method and included those results in the 30 March 2004 regulatory dossier lodged with the Therapeutic Goods Authority. Those results were, in part, directly comparable with the results obtained in 1998 and 2000 and recorded in the complete specification (see [60]). The results showed that tablets manufactured using the 1991 method obtained a greater percentage of the salt assay and were more stable than those made with the 2002 method. Dr Jaguelin said that the difference was small but showed that the tablets made with the 2002 method were slightly less stable than those made with the 1991 method. Dr Jaguelin said that even if she had been aware, as at 27 February 2003, of the 2002 method stability study results, she would not have been in a position to conclude that the 2002 method was preferable to the 1986 or 1991 methods for the purpose of producing more stable perindopril arginine tablets.

209 The primary Judge was satisfied that, as at 27 February 2003, neither Dr Jaguelin, nor anyone in Servier, knew of the stability study results for tablets made by the 2002 method, which results could not have been known until at least later in May 2003. Further, His Honour concluded, it was not possible to say that the 2002 method produced perindopril arginine with better stability than the 1986 or 1991 methods. However, his Honour also noted that *'[s]elf-evidently'* the person responsible for the decision to manufacture the 23.1 million tablets using the 2002 method must have believed that that method would result in a successful product. Nevertheless, his Honour noted at [69] that *'belief falls short of knowledge'*.

210 His Honour also expressed himself not satisfied that Servier had an obligation under s 40(2)(a) of the Act to disclose the 2002 method in the complete specification, but said that there was no reason why Servier could not include the description of that method if it was otherwise entitled to amend the complete specification.

211 The primary Judge noted (at [124]) that Servier did not call Ms Harris, nor did it offer an explanation for its failure to call her. His Honour inferred that any evidence she may have given concerning her recommendation and the then state of reasonable professional judgment of patent attorneys as to compliance with the best method requirement in s 40(2)(a) would not have assisted Servier's case. That, however, does not lead to a factual finding that Dr Jaguelin's state of mind accorded with that of Ms Harris. Dr Jaguelin was not asked directly whether upon receipt of the Harris letter she then apprehended that there was a separate best method requirement.

212 It is convenient to consider the primary Judge's reasoning in respect of each issue he identified.

Issue 1: The construction issue

213 The primary Judge concluded (at [134]) that the Court was empowered to amend a complete specification of a patent, subject to s 102 of the Act. His Honour concluded (at [137]) that s 105(1) of the Act conferred power on the Court to grant an amendment to a patent to remedy the failure to comply with the best method requirement as set out in s 40(2)(a). That reasoning on the construction issue is not challenged in the appeal.

Issue 2: The futility issue

214 The primary Judge rejected Apotex's and Actavis' argument, in respect of the futility issue, that the description of the best method cannot be amended under s 105(1) after the date of filing of the complete specification or, at the latest, after the grant of the Patent, for a number of reasons, which were as follows:

- Acceptance of that argument would extend the range of amendments that were not allowable beyond those specifically identified in s 102 and would narrow the power conferred by s 105(1) to grant an amendment in revocation proceedings. Such a construction would impose an unexpressed limitation on a broad remedial power conferred on the Court, contrary to ordinary principles of statutory construction.
- The use of the present tense in the ground of revocation in s 138(3)(f), viz. *'that the specification does not comply with subsection 40(2) or (3)'*, did not negate the

availability of an express power in s 105(1) to grant an amendment to a specification that does not comply with ss 40(2) or 40(3). To the contrary, his Honour said, the Parliament had conferred on the Court the power to amend a complete specification in proceedings for revocation of a patent. An amendment of a specification could be made in *'relevant proceedings'*, which these were, at any time before the making of the final order in the exercise of the discretion to revoke under s 138(3). If the complete specification were amended under s 105(1) before exercising the power to make an order, so that the specification after the amendment did comply with s 40(2) and (3), then the precondition for the exercise of the power to revoke under s 138(3)(f) would no longer exist. Such a construction would accord with the remedial purpose of s 105(1) and its express availability in proceedings for revocation. The opposing construction required the implication of a further unexpressed limitation on the plenary power in s 105(1) and failed to recognise that s 105(1) applies only in proceedings where the validity of the patent is in peril.

- The primary Judge agreed with the obiter dicta of French and Lindgren JJ (with whom Crennan J agreed on this issue) in *Pfizer* that the question of whether s 138(3)(f) permitted an order for revocation depended on whether the complete specification as amended (in that case to change the description of the best method) complied with s 40(2) at the time of the determination of whether to order revocation.
- Section 41 of the Act deals specifically with deposit requirements for micro-organisms in s 40(2)(a). Apotex and Actavis relied on s 41, which placed a date upon compliance. His Honour was of the view that this created a self-contained regime for satisfying the requirement in s 40(2)(a) to describe fully an invention of a micro-organism or involving its use, modification or cultivation.
- The full description of the best method was an included, but not exclusive, requirement of the full description of the invention required by s 40(2)(a). If an amendment to add a description of the best method were not possible by reason of s 105(1) then no part of the complete specification could be amended, contrary to the express words of that section. Further, it would deny s 105(1) any operation with respect to an amendment of the complete specification in relevant proceedings, contrary to the express wording of that subsection.
- In *Pfizer*, the majority in the Full Court held that the applicant for a patent must describe the best method known to it at the date of filing of the complete specification, but their

Honours explained that if the applicant had failed to describe the best method on the first attempt, s 104 permitted an amendment to be obtained from the Commissioner to correct the error. The discussion as to 'the latest date' was in respect of a description of the applicant's knowledge of the best method, not the latest date on which an amendment could be made. Thus, it is possible retrospectively to alter the description of the knowledge, the knowledge being possessed at some anterior point in time. Thus, an amendment could be made after the date of filing but not to add knowledge that the applicant only gained at a later time. Similarly, a person could not include the description of a best method which was not known until after the date of the grant of the patent.

- Matters such as the nature of the error, the circumstances in which it occurred and the reasons why the amendment was later sought are all material to the exercise of the Court's discretion in considering whether to permit amendment.

215 The primary Judge thus concluded that the Court has power under s 105(1) to grant an amendment of any part of a complete specification that is not prohibited by s 102 and s 105(4).

Issue 3: The Servier's knowledge issue

216 The primary Judge explained that both Apotex and Servier were bound by his decision that the complete specification failed to comply with s 40(2)(a) because it did not include the 1986 and 1991 methods and that an issue estoppel in the terms of the declaration that his Honour made in another earlier decision binds both Apotex and Servier. That declaration was:

> *1. The specification of Australian Patent 2003200700 does not comply with s 40(2)(a) of the Patents Act 1990 (Cth) because it fails to disclose the best method known to the patentee of performing the invention, being the following:*
>
> *(a) The arginine salt has been made in the following manner. 12 g (32.56 mmol) of perindopril (free form) and 5.67 g (32.56 mmol) of L arginine were mixed and then dissolved in 150 ml of permuted water. The resulting mixture was filtered on a sintered filter to eliminate insoluble particles. The filtrated solution was then lyophilised (freeze dried). The residue was taken up again in 150 cc of anhydrous ethyl ether, stirred for two hours and passed through a sintered filter again, before being dried in a desiccator. This resulted in a white crystalline product weighing 16.58 g.*
>
> *(b) The arginine salt has also been made in the following manner. 16.268 g (44.15 mmol) of free form perindopril was mixed with 7.306 g (41.94 mmol) of L arginine and 50 ml of permuted water. Those three ingredients were mixed in a 100 ml spherical flask, resulting in a semi-limpid solution. This was stirred for 15-20 minutes and evaporated until dry. The residue was retaken in a trituration using 150 ml of*

> *anhydrous ether. The solution was stirred overnight. Then the product was filtered under a vacuum, washed again with anhydrous ether and dried again in a desiccator under another vacuum. This produced 21.29 g of white crystalline substance, being perindopril arginine.*

217 His Honour also concluded that Actavis could not contest or ignore the preclusive effect of the issue estoppel said to have been created by that declaration because it had chosen not to be joined as a party and instead exercised its limited right to oppose the amendments sought by Servier. Nonetheless, his Honour said, Apotex and Actavis were entitled to oppose Servier's application on substantive and discretionary bases, including that any amendment might be futile.

218 His Honour then set out (at [155]) the matters he considered to be relevant to Servier's knowledge, which were as follows:

- There was no evidence that Servier knew, as opposed to believed, that the 2002 method was better than the 1986 or 1991 methods.
- Servier knew when perindopril arginine was used in the tablets studied that the 1986 and 1991 methods worked and produced the results set out in the Patent.
- Servier could not have known, as at 27 February 2003, that the 2002 method resulted in tablets that would have the same or better stability results than those given in the Patent because the stability study for those tablets would not be available until some time in May 2003.
- Knowledge is a different state of mind than belief.

219 Therefore, his Honour was not satisfied that Servier knew, as at the date of filing of the complete specification, that the 2002 method was as good as, or better than, the 1986 and 1991 methods.

Issue 4: The discretion issue

220 The primary Judge recorded the discretionary matters relied upon by Apotex and Actavis as follows:

- The application for amendment was made after the trial had concluded, when Servier was on notice of the asserted ground for revocation.
- Servier had not complied with its duty of full disclosure in respect of its knowledge of what was the best method known to it as at the filing date.

- Servier had delayed in seeking to amend and did not offer a satisfactory explanation for that delay.
- Servier had attempted to gain an advantage from its original decision to file the complete specification without disclosing the 1986 and 1991 methods.
- Servier had ignored the advice in the Harris letter in 2004.
- Servier had delayed its application to amend until some time after the decision on best method was made.
- Initially, Servier had not sought to include in the amendment the statement that each of the 1986 and 1991 methods had resulted in a white crystalline product.
- Servier had caused disadvantage to the public by depriving it of the knowledge of the 1986, 1991 and 2002 methods for the period between the filing of the complete specification and late 2013.
- Servier had only adduced evidence in connection with what it knew that Apotex and Actavis had already discovered from the forensic process, and led no evidence that would actually disclose the best method as known to it as at 27 February 2003.

221 As to the Harris letter, Servier submitted that Dr Jaguelin had formed the view that there was no basis for concern. First, because she had considered that the recommendation in the Harris letter went to sufficiency and, secondly, because in Europe an opposition based on sufficiency grounds had been dismissed.

222 The primary Judge expressed the opinion that the power in s 105(1) confers upon the Court an unfettered discretion to permit or refuse such amendments as are allowable and which may make the Patent allowable or enforceable. Nonetheless, his Honour said, a patentee must make out a case in favour of the exercise of that discretion. His Honour considered what had been said by courts in other cases in which amendments were considered. He referred also to the patentee's obligation of candour as to the reasons for seeking amendment.

223 The primary Judge accepted the force in the opponents' argument that Servier was on notice about the possible need to seek to amend the Patent after Apotex was given leave to amend its pleading to rely on the asserted failure to disclose the best method. His Honour was satisfied that any failure on the part of Servier to seek an amendment prior to the trial, and after the introduction of failure to state the best method as a ground for revocation, was an error reasonably made in good faith on the basis of the advice of senior counsel. His Honour traced

the history of the revocation proceeding and the late application to amend to include the best method issue, together with the effect of that application on the fixture of the hearing. His Honour was unpersuaded that Servier's failure to seek an amendment earlier in the course of the revocation proceeding had any substantive impact on the exercise of the discretion under s 105(1).

224 The primary Judge concluded that the obligation of disclosure was confined to explaining why Servier sought the amendment. In that regard, the primary Judge accepted Dr Jaguelin's evidence. The onus, his Honour said, then moved to the opponents in respect of the challenge that they made. His Honour found that they had not established that:

- Servier had knowledge that the 2002 method was as good as, or better than, the 1986 and 1991 methods;
- the 2002 method produced the alpha crystalline form;
- Servier had characterised any form of perindopril arginine; or
- Dr Jaguelin intended to gain some advantage by the non-disclosure of the 1986 and 1991 methods.

His Honour also concluded that there had been no relevant delay on the part of Servier in applying for the amendment after the publication of the best method decision.

225 However, his Honour then turned to the recommendation in the Harris letter and Dr Jaguelin's response to it. His Honour concluded that Dr Jaguelin's decision not to act on Ms Harris's clear recommendation but to *'see later'* was a calculated risk about a potentially very valuable asset, were the Patent granted without the recommended amendment. His Honour explained that, although she honestly did not consider it necessary to act on the recommendation, Dr Jaguelin did not suggest that, had she done so, Servier would have suffered any disadvantage because the amendment would have been simple and straightforward. His Honour concluded that he was not satisfied that it was reasonable for Dr Jaguelin to decide not to act on Ms Harris's recommendation.

226 The primary Judge referred to what was said by Aldous J in *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 561 (at 577) and applied by Merkel J in *Novartis AG v Bausch & Lomb (Australia) Pty Ltd* (2004) 62 IPR 71 (at [135]). Relevantly, Aldous J said that where there is a lengthy delay in seeking amendment a patentee must give a reasonable

explanation for the delay, even if there is no detriment occasioned by it. In that case there was an eight year delay in amending. Justice Aldous said:

> *'If there be delay in amending by a patentee who knows or ought to know of the need to amend, as is the position in this case, then he must establish a reason for his decision not to amend or to do nothing and also that the reason was reasonable.'*

Justice Aldous also referred to the public interest in ensuring that patents are amended promptly and observed that the absence of damage was not sufficient reason for delay as it disregards the public interest in the reliability of patents.

227 At [182], the primary Judge said:

> *'The policy of the requirement in s 40(2)(a) is that the patentee disclose, as part of the statutory bargain to secure the monopoly conferred by the patent, the best method of performing the invention known to him, her or it'*

His Honour concluded that the damage to the public interest involved in Servier's failure to disclose the 1986 and 1991 methods, even after Ms Harris's recommendation, was not reasonable and that it outweighed the proprietorial interest of Servier in being able to save the Patent from revocation under s 138(3)(f) of the Act.

228 Accordingly, his Honour did not accede to Servier's application to amend.

Leave to appeal

229 Servier seeks leave to appeal from the primary Judge's decision to refuse the proposed amendments. As that decision was an interlocutory one, s 24(1A) of the *Federal Court of Australia Act 1976* (Cth) requires that leave to appeal be granted prior to any appeal being heard. Leave will be granted where the decision below is attended by sufficient doubt and substantial injustice is likely to result if the decision is left in place: *Decor Corporation Pty Ltd v Dart Industries Inc* (1991) 33 FCR 397. Where the decision of the Court below in substance disposes of the matter, as the primary Judge's decision did here, the second limb will usually be satisfied. While we are not convinced that the first limb is satisfied here, we note that Apotex and Actavis do not object to the grant of leave. Accordingly, we propose to grant leave to appeal. Apotex has filed a draft notice of contention, to which we have also had regard.

Servier's submissions

230 Servier makes the following submissions, said clearly to reflect the authorities in both the United Kingdom and Australia, as to the discretion to permit amendment of a patent:

- The power to direct amendment is conferred on the Court for the benefit of the patentee. The essential bargain between the community and the inventor necessary to encourage invention and innovation would be broken if the public received the teaching without ceding the monopoly.
- The rationale underlying an exercise of the Court's discretion refusing permission to amend is the protection of the public from the abuse of monopolies. It is in this context that the patentee's conduct is relevant. An exercise of the discretion so as to refuse amendment is not based on moral or quasi-moral grounds.
- In considering whether to exercise the discretion so as to refuse amendment, the Court ought to take into account the proportionality of the alleged culpability of the patentee when compared with the effect of loss of protection for its invention.

231 Servier says that courts in the UK and Australia have found conduct on the part of patentees to amount to an abuse of monopoly and therefore as disentitling the patentee to amend its patent under s 105 and its UK equivalent where the conduct involves:

- *'culpable delay'* in seeking to amend (mere delay being insufficient), on the basis that in the meantime the patentee has behaved unreasonably by representing to the public that it has a valid claim when it knows the claim cannot be supported in its present form or, alternatively, lulling potential respondents and the public into a false sense of security by not applying to amend after being warned of objections; or
- *'covetousness'* in knowingly enforcing or propounding unjustifiably wide claims, whether before or by the amendment, thus deterring inventors and workers in the field from research and experiment.

232 Servier relies on the findings of fact in its favour, in particular:

- as to the knowledge and belief of Dr Jaguelin;
- that the failure to seek amendment prior to trial was an error reasonably made in good faith in reliance on Senior Counsel's opinion; and

- that Servier had not been guilty of any relevant delay in applying for the amendment after the publication of his Honour's reasons on the revocation action.

233 Servier challenges the primary Judge's reliance on the Harris Letter and Servier's response. In particular, it says that the primary Judge did not specify whether he was making a finding that the Harris Letter was a recommendation to include the best method known to Servier as at the filing date, or that it was so understood by Dr Jaguelin. Further, Servier says that his Honour did not specify whether the 'calculated risk' that he found that Dr Jaguelin took was based on her understanding that it was a recommendation concerning the best method requirement rather than a recommendation to include a method of manufacture for the purposes of sufficiency. Servier submits that the Harris Letter could not be construed as a recommendation to include the best method known to Servier of performing the invention as at the filing date. In particular, the letter:

- referred to a method of manufacture to satisfy the 'written description requirement';
- spoke as at the date that it was written, namely 3 September 2004;
- did not specify a method of manufacture known to the patentee as at the filing date; and
- did not specify that the method's inclusion was a necessity.

234 Further, Servier said that his Honour interpreted the letter by reference to the inferred subjective intention of Ms Harris, and by reference to the fact that she was not called, and he accepted that Dr Jaguelin did not understand that there was a best method requirement that needed to be satisfied and no contrary suggestion was put to her in cross-examination.

235 Servier submits that the evidence supports an explanation that Dr Jaguelin understood that the recommendation was directed to sufficiency, that she took a 'calculated risk' in that regard only and that she was not aware of a best method requirement.

236 Further, Servier relies on the primary Judge's finding that there was no demonstrated detriment to the public from the failure to disclose the 1986 and 1991 methods. Further, Servier relied on the finding that it had not intended to gain some advantage by the non-disclosure.

237 As to the inclusion in the proposed amendments of the 2002 method, Servier says that it was under no obligation to include this method and that its inclusion was only a response to the grounds of opposition to the amendment concerning the existence of a better method than the 1986 or 1991 methods.

238 While Apotex accepts that Dr Jaguelin did not know of the 2002 method, it points out that someone at Servier must have known of a better method, or at least a preferable one, because neither of the 1986 and 1991 methods was a method of manufacturing on an industrial scale, yet by the filing date, Servier had manufactured 23.1 million tablets of perindopril arginine. As the 2002 method was a commercial scale method, it was to be inferred that it was preferred by Servier and hence the best method, or certainly a better method, which was known to it.

Consideration

239 In *Les Laboratoires Servier v Apotex Pty Limited* (2010) 89 IPR 219 at [60], Emmett J (Kenny and Stone JJ agreeing) observed that there is no limitation in s 105 of the Act on the purpose for which an amendment may be directed, noting that s 104 provides that a patentee might ask the Commissioner for leave to amend for any purpose, including, but not limited to, removing a lawful ground of objection to a request or specification. However, as Kenny and Stone JJ said at [76], guidelines have been developed in the authorities to assist in the exercise of the discretion.

240 A number of matters may be accepted for the purposes of this appeal:

- The discretion in s 105(1) to direct the amendment of a patent in relevant proceedings is unfettered.
- Relevant proceedings include proceedings for revocation of the patent.
- Section 102 provides for amendments that are not allowable. The proposed amendments do not fall into any such category and are thereby not precluded by reason of s 102.
- In principle, amendments may be made to overcome invalidity.
- Failure to comply with s 40(2) is a ground of revocation for which a patent may be revoked.

241 The primary Judge set out many of the principles that can be drawn from the authorities. In particular, his Honour relied on the reasoning of the Full Court in *Pfizer* at [381]-[390] per French and Lindgren JJ to conclude that there was no basis for carving out of the scope of amendment the disclosure of best method based on policy considerations as to the timing of such disclosure, where the Act itself provides that a patent may be amended to remove a lawful ground of objection and for the limitation on amendment. His Honour (at [143]) explained

that, in his view, [379] in *Pfizer* was intended to convey no more than that an amendment in relation to best method could only reflect knowledge possessed at the time of filing:

> *'In other words, their Honours were seeking to clarify in [379] that when the complete specification described the best method known to the applicant, the description had to be of the method known at no later than the date of filing even if the description of that knowledge was inserted at a later date.'*

We note that the parties in the appeal agreed that the date of filing was the relevant date for the assessment of an applicant's knowledge.

242 While the power to amend should in appropriate circumstances be exercised in favour of the patentee, it bears mentioning that it will not always be possible to overcome a ground of revocation by an amendment. Accordingly, the ground of revocation sought to be overcome is also relevant to the way in which the discretion should be exercised. In the case of a failure to comply with the best method requirement, it would be necessary to take into account, in the exercise of the discretion, the reason for that obligation and the time at which it is meant to be fulfilled.

243 A number of principles have been established and discussed in detail in the authorities in the United Kingdom and in this Court with respect to amendment of granted patents, relevantly and in summary:

- The discretion exists for the benefit of the patentee.
- The onus to establish that amendment should be allowed is on the patentee.
- Generally, a permissible amendment (i.e. one which is permitted under the Act) will be allowed unless there are circumstances which would lead the court to refuse amendment.
- The patentee must make full disclosure of all relevant matters.
- The Court's focus is on a patentee's conduct, not the merit of an invention.
- Amendment should be sought promptly and where a patentee delays for an unreasonable period, the patentee has the onus of showing that it delayed on reasonable grounds, such as a belief, on reasonable grounds, that an amendment was not necessary.
- Unreasonable delay is a circumstance likely to lead to refusal of the amendment.
- In assessing delay, the time when the patentee was unaware and reasonably did not know of the need for amendment is not taken into account. The relevant delay is from

when the patentee knows of the likely invalidity, or has its attention drawn to a defect in the patent, or is advised to strengthen the patent by amendment. That is, amendment will not be permitted in cases where a patentee knows or ought to know that amendment should be sought and fails to do so for a substantial period of time. Thus the reasonableness of the conduct of the patentee is a relevant consideration when assessing delay.

- Mere delay is not, of itself, sufficient to refuse to exercise the discretion to amend. The fact of delay is, however, relevant to whether the respondent or the general public have suffered detriment.
- If a patentee seeks to take unfair advantage of the unamended patent, knowing that it requires amendment, then refusal of the amendment is likely.
- The proportionality of the asserted culpability of the patentee as compared with the effect of loss of protection for the invention should be considered.

244 These principles have been applied to amendments generally and operate as factors relevant to the exercise of the discretion to grant or refuse amendments. There may be other factors that are relevant in a particular case.

245 We would add that the nature of the amendment and the ground of invalidity sought to be overcome by it are important matters to be taken into consideration when exercising the discretion. In the present case, the amendment is not a narrowing amendment to defeat a piece of prior art. It is to remedy the failure to comply with an obligation that crystallised on the filing of the patent application or, in the alternative, on the grant of the patent.

246 It goes without saying that, to the extent that the primary Judge exercised his discretion to permit amendment, *House v The King* (1936) 55 CLR 499 applies.

247 Servier submits that the primary Judge made, essentially, contradictory findings concerning Dr Jaguelin. On the one hand, his Honour accepted that she held the view that amendment was unnecessary by reason of her own experience and, further, that she reasonably relied on senior counsel's advice to that effect. On the other hand, his Honour concluded that she took a calculated risk in ignoring the advice in the Harris Letter, being advice from the specialist patent attorney retained to advise on the content of the Australian Patent, which advice was to provide a description of the best method in the specification. There is no inconsistency. Dr Jaguelin acted on her own views and her own belief; she received advice to the contrary, which

she chose not to accept, but instead decided to wait and see what the examiners actually required.

248 Servier's submission that the Harris Letter related to sufficiency and not to best method should be rejected. The letter recommended the inclusion of a method of manufacture *'even if the manufacturing method is well known in the art'*. The Harris Letter was directed to the best method requirement, over and above what was required for sufficiency. Servier submits that it should be accepted that Dr Jaguelin believed that Ms Harris' suggestion went only to sufficiency and that the Court should draw the inference that this is all Ms Harris intended to refer to. However, Servier did not adduce evidence from Ms Harris on that subject.

249 Dr Jaguelin clearly understood the requirements for sufficiency, and that the inclusion of the reference to a classical method of salification satisfied that requirement. From her evidence and the correspondence with Ms Harris, she was also, as Apotex accepted, of the view that there was no obligation to include a description of the best method of performing the invention, where the invention was a product.

250 As the primary Judge found, Dr Jaguelin erred in forming the view that the proposed amendment was unnecessary. The primary Judge was not satisfied that Dr Jaguelin's decision to ignore the advice of her Australian patent attorney was reasonable. That decision was open to his Honour and formed the basis for his Honour's exercise of discretion. There was no demonstrated error of principle or fact, or a taking into account of an irrelevant consideration. There is no sufficient reason for a reconsideration of the exercise of the discretion pursuant to s 105(1) of the Act.

Conclusion

251 Servier has not established relevant error on the part of the primary Judge in the exercise of the discretion under s 105 of the Act to refuse the application to amend the Patent to overcome the finding that the Patent failed to disclose the best method known to the Patentee of performing the invention. In view of this conclusion, this part of Servier's appeal should be dismissed and it is not necessary to consider the notice of contention in any detail.

252 As we do not accept that his Honour's discretion miscarried in the decision to refuse amendment, there is no reason to canvass Apotex's alternative bases for such refusal in detail. The additional matters relied upon by Apotex would only arise if it were necessary for this

Court to re-exercise the discretion as to amendment. That necessity has not arisen. We simply record some of these matters.

Other grounds relied upon by Apotex as relevant to a discretion not to allow amendment

Other relevant matters that were not considered by the primary Judge (Notice of Contention, Grounds 11 and 12)

253 Apotex relies upon a number of matters in support of its contention that the primary Judge erred, in a *House v The King* sense, in rejecting Apotex's alternative bases for refusing the application to amend and submits that, on a re-exercise of the discretion, were it to arise, a number of matters would be relevant. The primary Judge rejected these matters as irrelevant considerations, because they did not arise following his Honour's conclusions on either the law or the facts. Given our conclusion at [251] above, we set out a summary of Apotex's submissions for completeness only.

254 As to the discretion to be exercised under s 105, Apotex submits that the Court should not exercise its discretion to direct the amendments for the following additional reasons:

- The amendments will be futile in that the ground of invalidity has been made out and the patent should be revoked.
- Allowing the amendment would be contrary to public policy and the law, both of which require the patentee to disclose the best method known to it of performing the invention at the date of filing of the patent. This submission is discussed in more detail below, being Apotex's futility argument.
- Servier has not shown, or attempted to show, that the proposed amendments would add the actual best method which was known to it at the filing date.
- Servier delayed in bringing the amendment application in circumstances where its conduct in doing so was unreasonable.
- Further, Servier sought to obtain, and did obtain, an unfair advantage by not disclosing the best method which was known to it at the filing date of the Patent application or as at the grant of the Patent.
- Servier's delay had caused detriment to the public.
- There was on Servier's part an absence of full and frank disclosure, insufficient production of information to the Commissioner and of documents to the Court.

Futility (Notice of Contention, Ground 1)

255 Apotex contends that it did not advance a case before the primary Judge that the Court's power to permit amendment under s 105 was limited, but that it advanced a case as to how the discretion ought to be exercised which his Honour failed to apprehend and address. The primary Judge considered that he had such power to consider the amendments proposed by Servier and that it was a matter of the exercise of discretion. Apotex does not challenge that conclusion.

256 Apotex submits that to allow the amendments would not cure Servier's failure to describe the best method as at the date of filing and that, accordingly, the amendment would be futile, such that, as a matter of discretion, the amendment should be refused. Fundamentally, Apotex's submission is that the date on which the best method must be described is the date of filing, being the same date on which the patent applicant's knowledge is tested. So, Apotex's logic goes, if the complete specification does not describe the invention fully, including the best method known to the applicant at the date of filing, it is not a valid complete specification and, therefore, cannot be a complete application on which a valid patent may be granted. Hence, Apotex's submission is that a failure to disclose the best method known at the date of filing, being the date of the patent under s 65 of the Act, cannot be cured by amendment.

257 Apotex relies, here, on the public policy as set out in the Explanatory Memorandum, which can be summarised, relevantly, as follows:

- The Amendment Act requires an applicant to meet the disclosure requirements at the time of filing of the complete specification.
- It is intended to avoid the situation where patent rights accrue in the period before the applicant has fully described the invention.
- Public policy is against a patentee gaining protection for the period before it adequately met its obligation to provide the public with a complete disclosure of the invention and thus avoiding creation of uncertainty for the public and for competitors in the period between publication of the patent specification and the grant. This was to be contrasted with the decision of the Full Court in *Pfizer* at [347] and [390] which held that an invention need only be fully described as at the date of the grant.
- In other countries, patent laws require disclosure as at the date of filing.

258 The amendment to s 102(1) is said in the Explanatory Memorandum to address the amendment of a complete patent specification after filing to add new material that would go beyond the disclosure contained in the specification at its filing date:

> *'An applicant would not be able to amend the specification to add any material that the hypothetical skilled person could not directly derive by reading the information in the specification as filed.'*

259 The Explanatory Memorandum continues to express the view that an applicant would not be able to expand the disclosure where the full description requirement was not met but would need to reduce the scope of the monopoly to accord with what had originally been disclosed. Apotex contends that the date on which the best method known to the patentee must be included is the date of filing (*Pfizer* at [379]).

260 Apotex submits that a failure to comply with that obligation cannot be cured by amendment at all or, alternatively, by amendment after grant.

261 Apotex submits that whichever the relevant date, being the date of filing of the complete specification, the date of grant or the date of commencement of proceedings, the Patent failed to comply with s 40(2) within the meaning of s 138(3)(f) at that time. Accordingly, even if the amendments were made, it has been established that it ought to be revoked and the proposed amendments are therefore futile as they cannot cure the grant of revocation.

262 Apotex acknowledges that acceptance of this submission would require this Court to take a contrary view to that of the Full Court in *Pfizer*. We record the submission for completeness. It is not necessary to consider it further in this appeal.

Failure to amend at trial (Notice of Contention, Grounds 2 and 3)

263 As to Servier's failure to amend the Patent at trial, Apotex submits, in summary:

- In principle, a patentee should not be allowed to amend after judgment except in exceptional circumstances. This accords with UK practice and was endorsed by the Full Court with respect to trade marks in *Woolworths v BP PLC (No 3)* (2006) 70 IPR 270. No such circumstances exist in this case.
- Amendment to insert validating amendments after a trial in which all claims have been held invalid should be refused as a matter of discretion, particularly where a claim would be likely to result in further challenge post-amendment.

- Generally speaking, a party should not be permitted to raise an issue which, acting reasonably, should have been raised in the proceedings before they were finally determined.
- The primary Judge took into account advice from Servier's senior counsel as to the best method requirement to conclude that Servier's error in not seeking to amend at trial was made in good faith on that basis, even though the note of advice did not address the question of amendment per se (rather it was concerned with an application to amend Servier's pleading) and was not provided to Servier. Accordingly, it was an irrelevant consideration and was, in any event, incorrect.
- There was no proper reason advanced for Servier's failure to apply to amend earlier, even in the alternative.
- The primary Judge considered that it was in the interest of the parties to have a prompt trial and this was an irrelevant consideration as the subsequent amendment application resulted in greater cost, inconvenience and delay, and the insistence that the trial date not be vacated caused Apotex to limit its case and thus resulted in forensic prejudice.

264 The primary Judge set out his reasons for the conclusion, based on the evidence, including unchallenged evidence, that any failure on the part of Servier to seek amendment of the Patent prior to the trial was an error reasonably made in good faith. His Honour did not consider that the delay which Apotex asserted was a relevant factor to take into account in the exercise of discretion (at [179]).

265 It is not necessary to consider this submission further in this appeal, having regard to the conclusion reached above at [251]. Nevertheless, we note that, whereas the relevance of Servier's delay in this case is a matter about which minds might reasonably differ, the primary Judge's conclusion as to the reasons for the delay were not shown to be in error in the sense of *House v The King*. If we had had to decide the matter for ourselves, we may well have taken a different view to his Honour on the question of delay and upheld Apotex's submission on that matter.

The 2002 method (Notice of Contention, Grounds 5 to 10)

266 Apotex also seeks to rely on alleged errors made by the primary Judge in respect of his treatment of the 2002 method. Apotex says that the proposed amendment does not *'overcome'* the finding that the 1986 and 1991 methods were not disclosed. Apotex points to the production

by Servier in 2014 of documents showing that, as at the filing date, it knew of a better form of perindopril arginine, being the alpha crystalline form, and the better method of making perindopril arginine, being the 2002 method. In that regard, Apotex reiterates objections that it made before the primary Judge as to the form of declaration made by his Honour in relation to the failure to include the best method known of performing the invention. Apotex seeks to have that declaration varied or set aside, essentially, on the basis that it was improperly made, in an apparent attempt to limit the matters which would be relevant to the discretion to permit amendment of the Patent and that, in any event, it was infelicitously expressed because it went further than the findings made by the primary Judge in the revocation decision.

267 Apotex also contends that even if Servier can overcome or address the findings in the primary Judge's reasons by amendment at this stage, Servier has not shown or attempted to show that the amendments would add the actual best method known to Servier at the filing date. His Honour found that the 1986 and 1991 methods were the *'better'* methods of which Servier was aware as at the filing date and Servier has led no evidence in respect of any method better than those methods. In particular, Apotex draws attention to Servier's case as to the 1986 and 1991 methods and submissions that they were not practicable on a large scale or in commercial production, which, together with the inclusion of the 2002 method in the proposed amendments, leads to the conclusion that Servier has not provided evidence directed to establish what was the best method known to Servier at the relevant date.

268 Apotex submits that the evidence establishes that Servier knew of a method of making perindopril arginine that was better than the 1986 and 1991 methods, namely the 2002 method, which yielded a form of perindopril arginine that was better than other forms. Despite this, Servier did not lead such evidence in the revocation proceeding and, indeed, emphasised the 1986 and 1991 methods, which were not in truth the best method known to Servier as at the filing date. It is clear from the specification that the form of perindopril arginine discovered by Servier was suitable for commercial use as a pharmaceutical composition and the 2002 method was directed to its commercial production.

269 However, Apotex accepted that Dr Jaguelin did not know of the 2002 method. Apotex submits that it is obvious that Servier was aware of the 2002 method prior to filing, even if Dr Jaguelin was not. It was the method used to manufacture, on an industrial scale, 23.1 million tablets. It was therefore superior to the 1986 and 1991 methods because of the stability of the resulting compound, or because of its success in commercial scalability, necessary to achieve the desired

outcome of the invention: a perindopril product stable over long term storage. Apotex challenges the primary Judge's conclusion in considering only the stability of the product of that method and the conclusion that there was no evidence that Servier knew, in contrast to believed, prior to the filing date that it was the best method.

270 Apotex says that Servier wishes to amend the specification to include the 2002 method, without demonstrating that it was the best method known to it as at the filing date. Apotex relies on the principle that the obligation is on the patentee seeking to amend to disclose all relevant matters and submits that Servier has demonstrated a clear failure to meet its duty of candour.

271 The primary Judge held that Apotex and Actavis failed to establish that Servier knew at the time of filing that the 2002 method was a better method of performing the invention than the 1986 or 1991 methods.

272 Again, we record this submission only for completeness as it is unnecessary to consider it further having regard to the conclusion reached above at [251].

Issue estoppel/Declaration (Notice of Contention, Ground 4)

273 Apotex appeals the content of the declaration made by the primary Judge in order, it says, to remove any arguable fetter on this Court's ability to take into account in a re-exercise of discretion, a consideration of the 2002 method. It is based on the submission that his Honour erred in finding that there was an issue estoppel, precluding consideration of the 2002 method.

274 Apotex asserts two forms of error. First, a finding by the primary Judge in the amendment decision that 1986 and 1991 methods were the best methods known, which had not been pleaded or found as a fact in the revocation decision. Secondly, that the primary Judge impermissibly used a declaration in order to summarise his Honour's reasons for judgment and to foreclose consideration of discretionary issues rather than to state the rights as between the parties, not as an error in the exercise of the power but about the form of the declaration. Apotex submits that it only had to prove a negative: that Servier had failed to provide the best method and did not have to prove what the best method was. Consequently, Apotex submits, a finding as to what was the best method was not indispensable to his Honour's finding and therefore there is no issue estoppel. Rather, it submits, the declaration should not, by declaring that the best method known to Servier were the 1986 and 1991 methods, be a finding of fact. Rather, the judgment was the order for revocation and the true issue estoppel is the failure to disclose the best method. The 1986 and 1991 methods were simply matters of evidence. That

evidence should not have founded a declaration, nor should it have precluded Apotex from relying on the 2002 method as a matter to be taken into account in the exercise of discretion in the amendment application.

275 In any event, Apotex says, an issue estoppel only operates inter partes and a relevant consideration in the exercise of the power to grant amendment is the interest of the public, such that the estoppel cannot affect the exercise of the statutory power. Further, Apotex submits, the primary Judge erred in holding that Actavis, which had not been a party to the revocation proceeding, was bound by the issue estoppel. As to Actavis, Servier argued that when Actavis joined after advertisement of the application to amend, which followed from the revocation decision, Servier invited it to join and to be bound by the findings and declarations, which it refused. However, Servier points out that if Actavis wished to relitigate the issue, it could have but at the stage of joining the proceedings, the findings that led to the amendment application had been made. In that circumstance, Servier submits, his Honour's declaration was appropriate.

276 Given the above conclusion at [251], it is not necessary for us to resolve this issue. The primary Judge's findings in relation to amendment as regards the operation of the declaration, or some other issue estoppel flowing from the revocation judgment is, in light of our conclusions above, only of possible relevance in relation to the issue of costs. It suffices to note at this juncture that we have not found it necessary to resolve this matter in addressing the appeals against the costs orders made by the primary Judge.

THE APPEAL IN RESPECT OF THE COSTS DECISION

277 Apotex and Actavis appeal and, if it be considered necessary, seek leave to appeal from the costs orders made by the primary Judge in the best method decision and the amendment decision. His Honour ordered that:

- Apotex pay 66.67% of Servier's costs of the proceedings, being the action for infringement and revocation of the Patent; and
- Apotex and Actavis pay 60% of Servier's costs of Servier's application to amend the Patent.

278 It will immediately be seen that despite the decision that the Patent was invalid, the successful party, Apotex, was ordered to pay the Patentee's costs and that although Servier was

unsuccessful in the application to amend the Patent, nearly two-thirds of its costs were paid. In neither case was Servier ordered to pay any of Apotex's or Actavis' costs.

The decision of the primary Judge

279 The reasons of the primary Judge in coming to this decision can be summarised as follows.

The infringement/revocation proceeding:

280 As to the costs of the infringement/revocation proceeding his Honour said:

- The Court has a discretion as provided in s 43(2) of the *Federal Court of Australia Act* and, in particular, under s 43(3)(e) to order costs against a party whether or not the party was successful in the proceeding.
- The decision as to costs will reflect a broad evaluative judgment of what justice requires (*Gray v Richards (No 2)* (2014) 89 ALJR 113 at [2]).
- While generally the discretion is exercised in favour of the successful party, there is no absolute rule that in the absence of disentitling conduct a successful party is to be compensated by the unsuccessful party. Nor is there any rule that there is no jurisdiction to order a successful party to bear the costs of the unsuccessful party (*Foots v Southern Cross Mine Management Pty Limited* (2007) 234 CLR 52 at [25]-[26]; *Oshlack v Richmond River Council* (1998) 193 CLR 72).
- Costs orders are not made to punish the unsuccessful party but are made as a necessary consequence of a party having created litigation in which it has failed (*Foots* at [27], [34]).
- Disentitling conduct is not necessary to enliven the power to make an order for costs against a successful party (*Kazar v Kargarian* (2011) 197 FCR 113 at [2]-[9] per Greenwood and Rares JJ).
- These principles apply in patent litigation (*Probiotec Limited v University of Melbourne* (2008) 166 FCR 30 at [45]-[50] per Rares J, with whom Finn and Besanko JJ agreed).
- There have been a number of patent cases where the successful party has received only a percentage of its costs, in view of the issues on which it has been unsuccessful.
- Apotex won on a discrete, single issue but it had litigated the validity of the Patent on many fronts.

- During the interlocutory stages and in the course of the trial, Apotex abandoned the challenges to the Patent on utility and sufficiency of description grounds.
- Apotex timed the commencement of proceedings to accord with its commercial interests in launching a competing, generic product.
- Most of the time at the trial, and in preparatory steps, was devoted to issues other than the best method issue, which involved around two days of the trial costs and a similar proportion of the pre-trial costs.
- Apotex's principal argument as to best method was available on the face of the Patent. At the trial, Apotex ran the issue in a sensible and confined way.
- Servier had to fight a case that was lengthy, complex and expensive and it won on many issues, although it ultimately lost a valuable patent.
- The costs order satisfied the justice of the case, reflecting *'the substantial success that Servier enjoyed.'*

281 The primary Judge acknowledged at [10] that while single Judges of this Court have ordered that the amount of costs awarded to the successful party be reduced, no Judge has ordered that the successful party should bear a portion of the unsuccessful party's costs.

The amendment proceeding

282 In addition, as to the costs of the amendment proceeding his Honour said:

- There is a general rule that the applicant patentee seeking an amendment ought to pay the costs of any opposing party in the litigation, as well as the costs of any third party opponent that exercises its right to intervene to oppose the amendment application, whatever the outcome on the issues raised. However, a general discretion with respect to costs orders remains.
- Parties should not be encouraged to pursue unmeritorious objections by a belief that they will get their costs paid in any event. Applications to amend, at least where the amendment is by deletion, are not truly comparable to the "indulgence" said to be involved in the amendment of pleadings (*Eli Lilly* at [25] per Heerey J).
- The occasion for the amendment *'is brought about by an error that the patentee seeks to correct in respect of its earlier choice in framing the wording of its patent, that identified its claimed monopoly'*.

- Whether the correction should be made and its precise terms are matters of public interest, having regard to the monopoly rights involved.
- Servier's departure from the ordinary course in seeking amendments after the trial, rather than before, should not affect the result.
- There is no *'encrusted'* rule that the patentee pay the costs of the proceedings and great injustice would be done to a patentee *'by having to meet a barrage of unmeritorious, time wasting, or substantively unsuccessful arguments that need never have been run'*.
- The discretion under s 43 of the *Federal Court of Australia Act* is unfettered.
- The opponents to the amendment lost on *'a large range of issues that they ran'*, including the argument that Servier had a wide obligation of disclosure, which caused the proceedings on the amendment application to be protracted, including by the filing of, and answers to, notices to produce.
- Time was taken up by the opponents' arguments on the construction of s 105 of the Act and on the reasons in *Pfizer*, although *'[n]either argument had any substance'*.
- Time was taken up by consideration concerning the 2002 method, as to which the opponents were unsuccessful.

283 Apparently with respect to both the revocation and amendment proceedings, his Honour referred to what was said in *Van der Lely* at 63, namely that:

> *'in appropriate cases, the costs order at the trial should reflect the extent to which significant sums of costs have been thrown away by reason of one party, albeit successful overall, raising and pursuing unsuccessful points.'*

Submissions with respect to leave to appeal

284 Apotex and Actavis each applied for leave to appeal from the orders made as to costs. Section 24(1A) of the *Federal Court Act* provides that an appeal shall not be brought from a judgment that is an interlocutory judgment unless the Court or a Judge gives leave to appeal. A judgment is final, as distinct from interlocutory, when it finally determines, in a legal sense, the rights of the parties to the proceedings.

285 Servier submits that the costs orders are not *'final'*.

286 The parties accept that the question of whether leave should be granted falls to be decided by the application of the test enunciated in *Decor v Dart,* that is, whether the decision from which

leave to appeal is sought is attended by sufficient doubt to warrant it being reconsidered by a Full Court and whether, assuming the decision to be wrong, substantial injustice would result if leave to appeal were refused.

287 Servier also submits that the primary Judge's discretion should not be re-exercised under the principles in *House v The King*.

288 Apotex's and Actavis' primary position is that leave to appeal is not required because the costs orders were final. Apotex submits that the fact that the costs orders were made at a different time from the declaration and the revocation of the patent cannot determine whether the orders are final or interlocutory. In any event, Apotex submits that if there is doubt as to whether leave to appeal is required, such leave should be granted. It submits that sufficient doubt attends the costs orders and that, self-evidently, substantial injustice would result if leave to appeal were refused because Apotex is otherwise liable to pay a substantial proportion of Servier's costs, in addition to bearing all of its own costs, notwithstanding its success in establishing that the patent should be revoked.

289 Actavis adds as a further matter to be taken into consideration what it terms the public interest, in that the present costs order would have the effect of discouraging persons from opposing patent amendment applications, which contradicts the purpose of inviting non-parties to be heard on such applications under s 105(2) of the Act and r 34.41 of the *Federal Court Rules*.

Consideration: The need to seek leave to appeal

290 Leave to appeal against costs orders may be required where:

- the substantive proceeding was discontinued;
- where orders are made as to costs thrown away by reason of an adjournment;
- where costs orders are made following a summary dismissal of a proceeding;
- where costs orders are made as to costs thrown away when a Court-ordered mediation is abandoned; or
- where orders are made as to costs of an application for an extension of time within which to file and serve a notice of appeal.

291 In this case, the costs orders were made as part of the final orders determining the rights of the parties in each of the proceedings concerning applications for revocation and amendment. Leave to appeal is not required. In *Probiotec* at [79], Rares J (with whom Finn and Besanko

JJ agreed) said that he was of the view that, as a judgment under s 24(1)(a) of the *Federal Court of Australia Act* includes an order, a costs order at the conclusion of a proceeding is a final order made in the exercise of the jurisdiction under s 43. Whether or not the order for costs was interlocutory, in our view sufficient doubt attends the decision and substantial injustice would be caused to Apotex and Actavis if the decision were wrong and leave, if necessary, were refused. Accordingly, to the extent that leave is required, it is appropriate that it be granted, hence our decision to grant such leave as was necessary on 12 August 2015.

Submissions with respect to the costs of the revocation proceeding

292 Servier's submissions supporting the order for costs can be summarised as follows:

- Pursuant to the principles of *House v The King* at 504 to 505, it is not sufficient if Judges comprising the appellate Court consider that, if they had been in the position of the primary Judge, they would have taken a different course.
- The fact that no single Judge of the Court has previously made an order that a successful party in patent proceedings bear a portion of the unsuccessful party's costs is irrelevant.
- There was no error in failing to apply the guideline that costs follow the event.
- The power to award costs under s 43 of the *Federal Court Act* is absolute and unfettered, save that it must be exercised judicially.
- The approach taken by the primary Judge is consistent with an approach outlined in Aldous W, Young D, Watson A and Thorley S, *Terrell on the Law of Patents* (13th ed, Sweet & Maxwell, 1982) at 14.195, citing *Badische Anilin und Soda Fabrik v Levinstein* (1885) 2 RPC 73 at 118 per Bowen LJ, who observed that if parties in an action raise issues on which they are defeated they ought to do it at their own expense.
- Apotex brought the proceedings for its own financial gain.
- The demands of the community for greater economy and efficiency in the conduct of the litigation should be reflected in the costs order.
- The primary Judge carefully exercised his discretion based on his familiarity with the way in which the trial was conducted.

Consideration: The costs of the revocation proceeding

293 The fact remains that Apotex was successful in establishing a ground of invalidity and, accordingly, that the patent was liable to be revoked. In order to deal with the best method

issue it was necessary for the Court to construe the patent from the perspective of the skilled addressee. That exercise required the identification of the common general knowledge, in particular:

- the evidence and submissions on how salts are made, including on crystallisation parameters;
- how those parameters can affect the final form of properties of a compound;
- polymorphism and hydration states were relevant to the best method issue as well as to other issues such as obviousness, fair basis, novelty and false suggestion, being issues in which Apotex was unsuccessful.

294 It is not the case that the issues could be segregated as his Honour said at [24]. It is not apparent that any of the issues raised and pursued by Apotex were obviously bad or unreasonably maintained. Apotex abandoned two of the grounds upon which it asserted invalidity after some reflection, which indicates that it chose not to pursue those grounds that it considered to be unlikely to succeed. However, in that regard, Apotex accepted that it did not succeed on its alternative grounds of invalidity and submits that the Court's discretion would not be misapplied if the Court discounted Apotex's entitlement to costs in the order of 25%, up to the date of the settlement offers.

295 The primary Judge did not find that any of the grounds of invalidity relied upon by Apotex were trivial, unreasonable or unmeritorious.

296 The primary Judge was correct to point out that the Court has a wide discretion in the award of costs. However, that does not mean that there are no principles or practices to be applied in exercising that discretion. Some of those principles are of general application in litigation; others are particularly applicable to complex litigation. Patent litigation frequently falls into this category. In some cases there are long standing practices that have developed arising from the nature of the proceeding. Applications for amendment of a patent are in this category.

297 There are two general approaches to the award of costs that have general application and have been the subject of numerous decisions:

(1) The successful party is generally entitled to its costs. That is, costs usually follow the event.

(2) It is also the case that a successful party may be awarded less than its costs, or there may be an order apportioning costs, on the basis of success on the issues.

298 This has been recently reiterated by the High Court (per French CJ, Kiefel, Nettle and Gordon JJ) in *Firebird Global Master Fund II Ltd v Republic of Nauru (No 2)* (2015) 90 ALJR 270 at [6], where their Honours observed that if the event of success cannot be seen as contestable, having regard to how separate issues have been determined, then:

> *'There are no special circumstances to warrant a departure from the general rule, and good reasons not to encourage applications regarding costs on an issue-by-issue basis, involving apportionments based on degrees of difficulty of issues, time taken to argue them and the like.'*

299 Section 138(3) of the Act provides a number of separate grounds on which a patent may be revoked. Proceedings for revocation of a patent commonly raise a number of those grounds. Each is recognised as important and if such a ground is established then the patent, which, if valid, grants a monopoly, is liable to be revoked as invalid. It is not only in the interests of the party seeking revocation that an invalid patent be revoked; it is also in the public interest. That is not to say, however, that a party should invoke grounds that cannot be properly and reasonably supported by consideration of the patent and, where relevant, by evidence or grounds which are not seriously arguable.

300 The practice has developed that where a party relies on grounds that are not established and where time has been expended and costs incurred as a consequence, that party, although it may ultimately be successful, might not recover all of its costs. This, in turn, may depend on whether evidence and argument can be separated. For example, evidence from the skilled worker in the art may be relevant to different grounds of revocation and to an understanding of the patent for the purposes of construction and disclosure. Further, the question of apportionment is a matter of discretion and generally does not lend itself to mathematical precision, by reference to time or to importance. In any event, as the primary Judge recognised, it has not hitherto been the case that such a successful party which obtains an order for revocation of the patent is ordered to pay the patentee's costs.

301 On the other hand, Courts have been increasingly concerned, generally, to use all proper means to encourage parties to consider carefully what matters they will put in issue in their litigation. This has led to decisions whereby the successful party does not recover all of its costs where it has been unsuccessful on a discrete issue or in what is decided to be an unmeritorious objection.

While it is acknowledged that, ordinarily, costs follow the event, the wide discretion in awarding costs has led to circumstances where a successful party who has failed on certain issues may be ordered to pay the other party's costs of them (as discussed in *Hughes v Western Cricket Association (Inc)* [1986] ATPR 40-748 per Toohey J), although warnings have been stated that care should be taken in such a course and consideration be given to whether the issues on which the successful party failed are clearly dominant or separable (*Waters v PC Henderson (Australia) Pty Ltd* (1994) 254 ALR 328 at 330 to 331 per Mahoney JA) and to whether the issues involved different factual enquiries in the one proceeding or multiple causes of action, even if based on a common substratum of fact.

302 Many of the authorities are discussed in *Hockey v Fairfax Media Publications Pty Limited (No 2)* [2015] FCA 750 per White J at [85] to [91]. In that case, his Honour found (at [100]) that the applicant failed on the *'principal focus at trial, and the parties' work which preceded it'*. However, White J noted that the submissions concerning that subject matter were not wholly discrete from the claims on which he succeeded and that he had some success on matters having a common substratum of fact and law. His Honour did not order him to pay some of the respondents' costs, but instead reduced the costs to which he was entitled.

303 Without amounting to an absolute rule, the principle remains that, subject to certain limited exceptions generally linked to the disentitling conduct of the successful party, a successful party in litigation is entitled to an award of costs (*Oshlack* per McHugh J at [67] to [68], in dissent but not in this aspect of the principle and with whom Brennan CJ agreed). That is not to punish the unsuccessful party but to compensate the successful party. There is no absolute rule that, in the absence of disentitling conduct, a successful party is to be compensated by the unsuccessful party, nor is there a rule that there is no jurisdiction to order a successful party to bear the costs of the unsuccessful party (*Oshlack* at [40] per Gaudron and Gummow JJ). However, the Courts have been slow to order a successful party to pay the costs where it has been unsuccessful on some issues. In *Mok v Minister for Immigration, Local Government and Ethnic Affairs (No 2)* (1993) 47 FCR 81, Keely J was of the view (at 84) that, without attempting to fetter the discretion, this power ought to be exercised only where the Court, on a consideration of all of the circumstances, has concluded that the raising of an issue by the applicant on which it has failed was so unreasonable that it is fair and just to make the order.

304 As the High Court (per Mason and Deane JJ, with whom Brennan J relevantly agreed) observed in *Norbis v Norbis* (1986) 161 CLR 513 at 519, discretionary remedies may be transformed

into remedies which are granted or refused according to well-settled principles which guide the exercise of a discretion. This transformation promotes consistency in decision-making, the need for which may be a countervailing factor to the width of the discretion. As Gageler J observed in *Comcare v PVYW* (2013) 250 CLR 246 at [139]:

> *'While a rule or principle developed by an appellate court to guide the exercise of a statutory discretion does not itself have the force of law, "[t]here may well be situations in which an appellate court will be justified in setting aside a discretionary order if the primary judge, without sufficient grounds, has failed to apply a guideline in a particular case" and "[w]here there is nothing to mark the instant case as different from the generality of cases, the failure will suggest that the discretion has not been soundly exercised"'.*
>
> (references omitted)

305 However, there is no limitation on the power granted in s 43 that is not found in the words used (*Probiotec* at [47]). The discretion is unconfined, except insofar as the subject matter, scope and purpose of the legislation indicate otherwise, yet it falls to be exercised judicially (*Probiotec* at [47], [50]).

306 We appreciate that the making of the costs orders was an exercise of discretion and that the principles in *House v The King* apply. In this case, we are of the view that the primary Judge acted upon a wrong principle in awarding costs on the basis of success as to issues and not starting from the position that the successful party is entitled to its costs. Further, in considering the success and failure on individual issues, his Honour failed to consider the extent to which there was a common substratum of fact in respect of issues on which Apotex succeeded and failed. Moreover, his Honour awarded costs on the success of the issues raised without full consideration as to whether the raising of those issues was justified.

Submissions with respect to the costs of the amendment application

307 As to the costs of the amendment application, Servier submits, in addition to those submissions detailed above, that, in summary:

- The primary Judge carefully exercised his discretion.
- The primary Judge did not err in holding that the costs order against Apotex and Actavis should reflect that the argument that the 2002 method was a better method than the 1986 or 1991 methods was unsuccessful for the reasons given by the primary Judge.

308 Apotex and Actavis point out that the primary Judge did not find that any of their arguments, in the amendment proceeding were trivial, unreasonable or unmeritorious. Accordingly, it submits the ordinary rule, that the patentee bear the costs of an amendment application, should apply. Apotex also takes issue with the primary Judge's analysis of the timing required for the hearing of each of the issues raised in the amendment application and the time allocated to Apotex's arguments.

309 Apotex also points out that Servier amended its application twice. The first amendment was proposed to specify that the earlier method produced a crystalline substance; the second amendment was proposed to include the 2002 method. Despite the fact that it did not succeed in its arguments as to the 2002 method, which took a significant portion of the hearing and of submissions, Apotex points out that this was so because of Servier's decision to seek to include that method in the Patent and to file further evidence in support of it. Apotex submits that, in that context, its reliance on arguments concerning that method was not unreasonable.

310 Actavis responded to an advertisement published by the Australian Government (in the guise of IP Australia) in the *Australian Official Journal of Patents (Supplement)* (**Official Journal**) concerning the amendment application. Actavis gave notice that it would exercise its entitlement under r 34.41 of the *Federal Court Rules* to oppose the amendment application. Actavis submits that the costs order was unreasonable and plainly unjust, that the primary Judge failed to apply the principle of consistency, that he acted upon a wrong principle and took into account irrelevant considerations, as well as failing to take into account relevant considerations, and mistook facts relevant to the exercise of his discretion as to costs. Actavis also submits that it would be contrary to the public interest to allow the costs order to stand. Actavis points out that an opponent's role in serving the public interest is reflected in the requirement that an amendment application inviting opposition be advertised in the Official Journal.

Consideration: The costs of the amendment application

311 In *Apotex Pty Ltd v Les Laboratoires Servier (No 3)* [2009] FCA 1069 Bennett J rejected a submission that the opponent should have less than its full costs (on a party-party basis) because some of its arguments (which consumed half of the hearing time) were unsuccessful. Her Honour observed (at [5]) that, while the opponents in *Wimmera Industrial Minerals Pty Ltd v RGC Mineral Sands Ltd* (12 November 1997, Federal Court of Australia, Sundberg J, unreported) and in *Gambro Pty Ltd v Fresenius Medical Care South East Asia Pty Ltd* [2000]

FCA 407 received less than their full costs, some of their objections were found to be unnecessary, trivial or unreasonable.

312 As to the costs awarded on the amendment application, his Honour failed to take into consideration the principle that amendment of the patent is an indulgence to the patentee and the practice that has long followed that principle. It has long been accepted (for example, *In the Matter of British Thomson-Houston Company Limited's Patent* (1936) 53 RPC 225 at 269 per Luxmoore J) that amendment to a patent is an indulgence to the patentee, who should therefore pay the costs. As put by Emmett J in *Les Laboratoires Servier v Apotex Pty Ltd* (2010) 89 IPR 219 at [59], the power conferred on the Court by s 105, to allow a patentee to validate what would otherwise be an invalid or partially invalid patent, is for the benefit of the patentee, but the exercise of that power is an indulgence. This does not necessarily extend to amendment by deletion (*Eli Lilly* at [25] per Heerey J). Further, as Luxmoore J said, the Court should not discourage people from assisting the Court and offering *'such criticisms as are proper to put forward'*. A similar approach towards an opponent of amendment was taken in *ICI Chemicals & Polymers Ltd v Lubrizol Corp Inc* (1999) 47 IPR 110 by Emmett J, who observed (at [19]) that if there had been no opponent, it would have been desirable for the Court to invite a contradictor.

313 This practice means that the award of costs, simply on the basis that certain grounds of opposition to the amendment were unsuccessful, is an approach which is incorrect in principle, where none of the grounds raised were found to be trivial, unmeritorious or unreasonable.

314 The primary Judge also failed to take into account Actavis' confined role in the amendment application. Actavis gave notice of its intention to oppose the amendment application at a time by which Servier had taken steps and incurred costs arising from Apotex's opposition to the amendment application. Actavis filed no affidavit evidence and did not participate in the joint experts' process. While Actavis cross-examined Dr Jaguelin, Actavis and Apotex did not engage in double cross-examination.

315 Further, we note that it was Servier itself that applied to include the 2002 method in its proposed amendment. That reasonably raised the question whether Servier knew it to be a better method than the 1986 or 1991 methods. That, in turn, caused the opponents reasonably to seek disclosure of relevant documents, which the primary Judge recognised in granting leave to serve notices to produce such documents. All of this contributed to the length and cost of the

amendment proceeding, yet it involved no conduct on the part of the opponents which could reasonably be impugned.

316 It follows that his Honour erred in making the order that Apotex and Actavis pay 60% of Servier's costs of the amendment proceeding.

317 As to the significance of the declaration and issue estoppel it was said to create, it is not apparent from his Honour's costs decision that this matter was taken into account as a relevant factor when exercising the jurisdiction under s 43. We do not think it necessary, in light of our conclusions, to consider it further. That being the case, it is unnecessary for us to resolve Apotex's cross-appeal in relation to the form and appropriateness of the declaration of 29 May 2014.

The offer of compromise and the *Calderbank* letter

318 Shortly before the trial commenced, Apotex made two offers of compromise which were substantially the same, the first under r 25.14(3) and the second as a *Calderbank* offer. The offer, relevantly, was that:

- Apotex's application for revocation be dismissed;
- Servier's claim for infringement also be dismissed;
- the interlocutory injunction be discharged and Servier be released from its undertaking as to damages;
- each party bear its own costs; and
- Servier grant Apotex a royalty-free, non-exclusive licence under, and for the remainder of the term of, the patent, including any applicable extension in terms substantially as set out in the offer.

319 Each offer was rejected by Servier.

Submissions with respect to the offer of compromise and the *Calderbank* letter

320 As to Apotex's offer of compromise and the *Calderbank* letter, Servier's submissions support the reasoning of the primary Judge. Servier submits that Apotex was not as successful as its offer under the rules and that its refusal of the *Calderbank* offer was reasonable.

321 Apotex submits that the result of the proceeding is a more favourable outcome to it than the terms of the offer of compromise made under the rules because:

- the Patent will be revoked;
- Apotex does not have to enter into a licence with Servier, albeit a royalty free one; and
- Servier is now liable pursuant to the undertaking as to damages which it provided so that it could obtain orders enjoining Apotex from offering its generic product.

322 Apotex submits that even if the Court were not minded to conclude that the outcome of the litigation was clearly better for Apotex than the offer, so as to attract the *'automatic consequence'* under the rules, the Court ought to have considered that offer in exercising its general discretion to award costs, as the Full Court did in *Novozymes A/S v Danisco A/S (No 2)* [2013] FCAFC 55, that being a relevant consideration that his Honour was obliged to take into account in the exercise of discretion. Apotex submits that the outcome which eventuated was better than the offer that it made to Servier, in particular, because it was entitled to claim under the cross-undertaking for three years of being kept out of what is, admittedly, a multi-million dollar market.

323 Apotex submits that its offer represented the highest that a revoker or potential infringer could offer in patent proceedings, short of capitulation and that a failure to take its offer into consideration is contrary to the public interest, as it is not possible to conceive of an offer that would, short of capitulation, enable a compromise in patent proceedings which could attract costs consequences.

Consideration: The offer of compromise and the *Calderbank* letter

324 The primary Judge concluded that it was not possible to ascertain, on the available material, whether the orders revoking the Patent and as to costs amounted to a judgment that was more favourable than the outcome proposed in the offer. Had Servier accepted the offer, his Honour noted, there would have been no trial, no further exposure of either party to further solicitor/client costs and no exposure on the undertaking as to damages for three years' of Apotex's lost profits. His Honour said that the financial value of the undertaking was not susceptible to evaluation on the material available. There was no evidence of what damages Apotex may have been entitled to claim, especially with other generic manufacturers on the market.

325 The automatic consequences of a costs order in favour of the applicant under r 25.14(3) depends upon the existence of the fact that the Court's judgment is actually more favourable to the applicant, here Apotex, than the terms of the offer. There was no information at all as to what

Apotex's financial position would have been had it had the right to exploit the non-exclusive licence. The primary Judge was, therefore, not satisfied that the operation of r 25.14(3) was engaged.

326 As to the *Calderbank* offer, the primary Judge concluded that Apotex had not demonstrated that Servier's refusal was unreasonable. His Honour said that the fact that the two sides held genuinely different views as to their respective prospects of success did not render Servier's refusal unreasonable or *'imprudent or plainly unreasonable'* to use the expression of Besanko and Jessup JJ in *Elecspess Pty Limited v LED Technologies Pty Limited* (2013) 215 FCR 95 at [16].

327 The primary Judge was of the view that the available evidence was insufficient to come to the necessary conclusion that the offers of compromise represented a more or less favourable position for Apotex than the alternate result. Accordingly, this uncertainty meant that it could not reasonably be taken into account in Apotex's favour as a discretionary matter under s 43.

328 Apotex has not established that his Honour's consideration was in error.

Conclusion in relation to costs

329 For these reasons, we are of the view that the primary Judge's discretion in the awarding of costs in each of the revocation and amendment proceedings miscarried and was erroneous within the principles of *House v The King,* and that it is appropriate for this Court to intervene. Accordingly, it is necessary for this Court to determine the appropriate orders as to costs.

330 As to the revocation proceeding, taking account of the issues on which Apotex was unsuccessful, but also having regard to the facts, evidence and submissions that were applied to those issues, and the best method issue on which it was successful and, importantly, Apotex's success in establishing that the Patent is invalid, Servier should pay 40% of Apotex's costs.

331 As to the amendment proceeding, taking account of the nature of a patentee's application to amend its patent and the course of that application, including the fact that Apotex was only successful in opposing the amendment on one basis, namely the Harris Letter, Servier should pay 75% of Apotex's and Actavis' costs of the amendment application.

CONCLUDING REMARKS AND ORDERS TO BE MADE

332 Having regard to the findings which we have made above, it is unnecessary for us to determine the following:

- Apotex's notice of contention in proceeding number NSD 247 of 2015;
- Apotex's notice of cross-appeal in proceeding number NSD 247 of 2015; and
- Apotex's notice of contention in proceeding number NSD 241 of 2015.

333 Therefore we do not make orders in respect of these matters.

334 It follows from what we have said above that Servier should pay Apotex's and Actavis' costs of the appeal.

335 The orders to be made in the different proceedings are as follows:

Proceeding number NSD 247 of 2015 (**the revocation appeal**)

1. The appeal be dismissed.
2. Servier pay Apotex's costs of the appeal.

Proceeding number NSD 241 of 2015 (**the amendment appeal**)

1. Grant Servier leave to appeal.
2. The appeal be dismissed.
3. Servier pay Apotex's and Actavis' costs of the appeal.

Proceedings numbered NSD 305, 307, 346 and 347 of 2015 (**the costs appeals**)

1. The appeals be allowed.
2. Set aside Orders 1 and 2 made on 24 March 2015 in proceeding number NSD 51 of 2012 and in lieu thereof order that in proceeding number NSD 51 of 2012:

    '1. Servier pay 75% of Apotex's and Actavis' costs of the application to amend Australian patent no 2003200700.

    2. Subject to Order 1, any existing orders as to costs and undertakings as to costs thrown away, Servier pay 40% of Apotex's costs of the proceedings.'

3. Servier pay Apotex's and Actavis' costs of the costs appeals.