FEDERAL COURT OF AUSTRALIA

Actavis Pty Ltd v Orion Corporation [2016] FCAFC 121

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| Appeal from: | *Orion Corporation v Actavis Pty Ltd* [2015] FCA 909  *Orion Corporation v Actavis Pty Ltd* *(No 2)*  [2015] FCA 1026  *Orion Corporation v Actavis Pty Ltd (No 3)*  (2015) 116 IPR 102; [2015] FCA 1373 |
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| File number: | NSD 1207 of 2015 |
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| Judges: | **ALLSOP CJ, NICHOLAS AND YATES JJ** |
|  |  |
| Date of judgment: | 9 September 2016 |
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| Catchwords: | **PATENTS** – validity of claims – whether relevant claims fairly based on the matter described in the specification – whether relevant claims clear  **PATENTS** – infringement – method claims  **PATENTS** – standing to sue – whether second respondent an exclusive licensee – whether third respondent has standing to sue for infringement – whether third respondent a proper party to the cross-claim for revocation |
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| Legislation: | *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth)  *Patents Act 1990* (Cth) ss 40, 120, 139, 187, Sch 1  *Patents Regulations 1991* (Cth) reg 19.1 |
|  |  |
| Cases cited: | *Bristol-Myers Squibb Co v Apotex Pty Ltd (No 5)*  (2013) 104 IPR 23; [2013] FCA 1114  *Bristol-Myers Squibb Company v Apotex Pty Ltd*  (2015) 228 FCR 1; [2015] FCAFC 2  *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260; [1994] FCA 396  *Emory University v Biochem Pharma Inc*  (1998) 42 IPR 35; [1998] FCA 915  *Lockwood Security Products Pty Limited v Doric Products Pty Limited* (2004) 217 CLR 274; [2004] HCA 58  *Norman v Federal Commissioner of Taxation*  (1963) 109 CLR 9; [1963] HCA 21  *Sharrment Pty Ltd v Official Trustee in Bankruptcy*  (1988) 18 FCR 449; [1988] FCA 266  *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth*  [2011] AIPC 92-428; [2011] FCAFC 132 |
|  |  |
| Date of hearing: | 15, 16 February 2016 |
|  |  |
| Registry: | New South Wales |
|  |  |
| Division: | General Division |
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| National Practice Area: | Intellectual Property |
|  |  |
| Sub-area: | Patents and associated Statutes |
|  |  |
| Category: | Catchwords |
|  |  |
| Number of paragraphs: | 258 |
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| Counsel for the Appellants: | Mr SCG Burley SC with Mr JS Cooke |
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| Solicitor for the Appellants: | Ashurst Australia |
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| Counsel for the Respondents: | Mr C Dimitriadis SC with Mr C Burgess |
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| Solicitor for the Respondents: | Clayton Utz |

ORDERS

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|  | | NSD 1207 of 2015 |
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| BETWEEN: | ACTAVIS PTY LTD (ACN 003 854 626) (and another named in the Schedule)  First Appellant | |
| AND: | ORION CORPORATION (and others named in the Schedule)  First Respondent | |

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| JUDGES: | ALLSOP CJ, NICHOLAS AND YATES JJ |
| DATE OF ORDER: | 9 September 2016 |

THE COURT ORDERS THAT:

1. By 4.00 pm on 23 September 2016, the parties are to bring in agreed orders giving effect to these reasons, including on the question of costs.
2. In the event that they are unable to agree, the parties are to provide drafts of the orders they propose, supported by written submissions not exceeding three pages in length, by 4.00 pm on 30 September 2016.
3. Until further order, and except as provided in Order 4, publication or other disclosure of paragraphs [94] and [95] of the reasons for judgment published today as *Actavis Pty Ltd v Orion Corporation* [2016] FCAFC 121 (**the reasons**) be prohibited.
4. Publication or other disclosure of paragraphs [94] and [95] of the reasons may be made to:
   1. persons authorised by the appellants; and
   2. the external legal representatives, internal legal representatives, external patent attorneys and internal patent attorneys of the respondents who have signed a confidentiality undertaking in respect of documents designated by the appellants as confidential which were provided to Clayton Utz on 6 November 2013.

**THE COURT NOTES THAT:**

1. Orders 3 and 4 are necessary to prevent prejudice to the proper administration of justice.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

REASONS FOR JUDGMENT

THE COURT:

# Introduction

1. This appeal is from judgments given on 21 August 2015, 16 September 2015 and 4 December 2015 in a proceeding commenced by the respondents against the appellants for infringement of Patent No. 765932 (**the patent**).
2. The first respondent, Orion Corporation (**Orion**), is the patentee. On 7 March 2014, Orion granted a licence of the patent (**the 2014 licence**) to the second respondent, Novartis Pharma AG (**Novartis**). On 11 March 2014, Novartis granted a sub-licence (**the 2014 sub-licence**) to the third respondent, Novartis Pharmaceuticals (Australia) Pty Limited (**Novartis Australia**).
3. In the proceeding below, the respondents alleged that the appellants had threatened to infringe various claims of the patent by seeking to market, in Australia, certain pharmaceutical products containing entacapone, levodopa and carbidopa   
   (**the Actavis products**). The Actavis products were indicated for the management of patients with Parkinson’s disease.
4. The appellants denied infringement and cross-claimed for revocation of claims 1, 2, 11, 12, 13, 14, 17, 18 (insofar as it is dependent on claim 17), 19, 20, 21 and 22 (insofar as it is dependent on any one of claims 1, 2, 11, 19, 20 and 21) of the patent on various grounds, not all of which are relevant to this appeal.
5. On 21 August 2015, the primary judge published reasons for judgment in which he found that all the challenged claims are valid and that the appellants had threatened to infringe claims 17, 18, 19, 20 and 21 of the patent: *Orion Corporation v Actavis Pty Ltd* [2015] FCA 909 (**Reasons 1**). Unless stated otherwise, all pinpoint references in these reasons to paragraphs of the primary judge’s reasons are to Reasons 1.
6. On 16 September 2015, the primary judge published reasons for judgment containing a confidential annexure, in which his Honour provided more detailed reasons for finding that the appellants had threatened to infringe claim 17 of the patent: *Orion Corporation v Actavis Pty Ltd (No 2)* [2015] FCA 1026 (**Reasons 2**).
7. On 4 December 2015, the primary judge published reasons for judgment in which he made certain findings about the legal effect of the 2014 licence and the 2014 sub-licence under the *Patents Act 1990* (Cth) (**the Act**) and the entitlement of Novartis and Novartis Australia to sue the appellants for infringement: *Orion Corporation v Actavis Pty Ltd (No 3)* (2015) 116 IPR 102; [2015] FCA 1373 (**Reasons 3**). It will be necessary for us to return to consider the primary judge’s findings in this regard. In the meantime, it is not necessary for us to distinguish between the three respondents.

# Background

1. Parkinson’s disease affects the sufferer’s ability to initiate movement voluntarily. It is characterised by slowness or lack of movement, rigidity of the limbs or trunk, and tremor of body parts when at rest.
2. Dopamine is a neurotransmitter. Parkinson’s disease is associated with a depletion of dopamine in the brain. This depletion can be reversed or reduced by administering an amino acid called D,L-dopa. D,L-dopa is partially converted to dopamine in the brain by an enzyme called DOPA decarboxylase (**DDC**).
3. The administration of D,L-dopa in large doses can produce serious, unwanted side effects.   
   L-dopa (levodopa) is an isomer of D,L-dopa. It is effective in treating Parkinson’s disease and can be administered in markedly lower doses than D,L-dopa.
4. Carbidopa is a DDC inhibitor. It inhibits the action of DDC in the peripheral tissues, but not in the brain. It protects levodopa from degrading while it travels through the body. It does not cross the blood-brain barrier with levodopa. The standard therapy for Parkinson’s disease using levodopa invariably consists of using levodopa with carbidopa (or another   
   DCC inhibitor, benserazide) in particular fixed dosage ratios. This has been the position since about 1974. The consequence is that, when administered with a DCC inhibitor, a lower dose of levodopa can be used.
5. In the body, levodopa is also degraded by an enzyme called catechol O-methyl transferase (**COMT**). Administering levodopa with a COMT inhibitor will increase the amount of levodopa that reaches the brain. This has been known since at least June, 1999. Entacapone is a COMT inhibitor.
6. Thus, the pharmacological effect of administering levodopa with carbidopa and entacapone is to protect the levodopa from being degraded during its passage through the body so as to increase the amount of the levodopa that is able to cross the blood-brain barrier for conversion into dopamine.

# The patent specification

1. In describing the field of the invention, the complete specification of the patent (**the specification**) says that the invention relates to new pharmaceutical compositions comprising entacapone, levodopa and carbidopa (or their pharmaceutically acceptable salts or hydrates), including an oral solid fixed dose combination; to a method of preparing such compositions; and to the use of the compositions in a therapeutic method: page 1, lines 4-10.
2. By way of background, the specification discloses that levodopa and carbidopa are the most commonly used drugs in the treatment of Parkinson’s disease and that they are available for administration in the form of combination tablets. These tablets are taken several times a day with a separate entacapone tablet. The specification says that patient compliance can be improved significantly by using a fixed dose combination of entacapone, levodopa and carbidopa: page 2, lines 7-12.
3. The specification says that, so far as the patentee is aware, no patent or other publication describes an oral solid composition comprising entacapone, levodopa and carbidopa or their pharmaceutically acceptable salts or hydrates: page 3, lines 3-6.
4. In the description which follows, we will only refer to the combination of entacapone, levodopa and carbidopa, it being understood that this description is to be taken as including a reference to the pharmaceutically acceptable salts and hydrates of these active agents.
5. The specification discloses the desirability of releasing entacapone, levodopa and carbidopa from the oral composition as soon as possible after ingestion. However, it is very difficult to adjust the absorption of the three different active agents. The specification discloses that, usually, in practice, the absorption of one active agent may decrease, while another increases. The specification also teaches the importance of considering numerous factors (such as the bioavailabilities of the active agents and the stability of the composition) when selecting appropriate excipients, disintegrants and other auxiliary agents to be used in a composition containing several active agents.
6. When summarising the invention, the specification states (at page 3, lines 13-21):

Applicants have discovered that entacapone, levodopa and carbidopa, or their pharmaceutically acceptable salts or hydrates, can be combined into one oral solid composition with particularly interesting properties.

The invention thus provides an oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa, or pharmaceutically acceptable salts or hydrates thereof, and comprising at least one pharmaceutically acceptable excipient (hereinafter referred to as a composition according to the invention), which has i.a. preferable stability and bioavailability characteristics and which is easy to swallow.

1. The appellants place particular significance on this passage. They submit that the second paragraph stands as, in effect, a consistory statement which confines the invention to an oral solid fixed dose composition of entacapone, levodopa and carbidopa that has preferable stability and bioavailability characteristics, with ease of swallowing.
2. The respondents also place particular significance on this passage. They submit that the invention described in the first paragraph of the passage is a three-in-one composition of entacapone, levodopa and carbidopa with particularly interesting properties. The second paragraph then defines “a composition according to the invention” as a composition with pharmacologically effective amounts of the three active agents together with at least one pharmacologically acceptable excipient. The respondents say that this paragraph conveys that there are preferred embodiments of the invention that are able to achieve preferable stability, bioavailability and ease of swallowing, which embodiments are then described in succeeding passages of the specification.
3. Immediately following the passage at page 3, lines 13-21, the specification discloses a particular embodiment in which at least one pharmaceutically acceptable excipient is sugar alcohol (preferably, mannitol), starch (preferably, maize starch) or sugar alcohol and starch: page 3, lines 22-27.
4. The specification discloses another embodiment in which microcrystalline cellulose (**MCC**) is not used as an excipient: page 4, lines 1-5.
5. The summary of the invention then turns to consider the question of bioavailability.   
   The specification states (at page 4, lines 6-15):

Applicants have found that a particularly interesting way to increase the bioavailability of carbidopa from an oral solid composition comprising entacapone, levodopa, and carbidopa is to add carbidopa separately, for instance by granulating first levodopa and entacapone together and then adding carbidopa to these granules separately.

Accordingly, the invention further provides an oral solid composition comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or pharmaceutically acceptable salts or hydrates thereof, and a pharmaceutically acceptable excipient, wherein a substantial portion of carbidopa is separated from entacapone and/or levodopa.

1. The specification discloses that there are several techniques to accomplish this separation. One technique is to granulate entacapone and levodopa together, and then add carbidopa separately “as such or in a form of granules”: page 4, lines 16-19.
2. The summary of the invention says that the oral solid composition “includes a tablet, a capsule and the like”: page 5, lines 3-4. However, a tablet form is preferred.
3. The summary also says that the invention provides a method of treating Parkinson’s disease by administering “an oral solid composition according to the invention” (page 5, line 8) up to, for example, eight to ten times per day, and an oral solid composition for the treatment of Parkinson’s disease in different stages of the disease.
4. The specification includes a number of figures (Figures 1 to 6) showing, respectively, entacapone, levodopa and carbidopa plasma concentrations after a single dose of certain described formulations or compositions (Formulations 1 to 4) containing the three active agents. Two other formulations (Formulations 5 and 6) are also disclosed.
5. The specification includes three examples (Examples 1 to 3) with corresponding tables (Tables 1 to 3). These tables list the ingredients of each exemplified formulation.
6. Example 1 was designed to assess the absorption in healthy volunteers of the active agents in two fixed dose combination tablets (Formulations 1 and 2) compared to the separate administration of entacapone (200 mg tablet) and levodopa/carbidopa (100/25 mg tablet) (**the reference products**). In Formulation 1, the combination tablets were prepared by wet granulating all the active agents at the same time. In Formulation 2, the combination tablets were prepared by dry granulating (compaction granulating) all the active agents at the same time. The blood plasma levels of entacapone (Figure 1), levodopa (Figure 2) and carbidopa (Figure 3) respectively were measured in the volunteers after Formulation 1, Formulation 2 and the reference products were administered. It was found that, for Formulation 1, the bioavailability of carbidopa was too low compared to the reference products. For Formulation 2, the bioavailability of carbidopa was acceptable. However, this formulation included polyethylene glycol which was found to cause stability problems.
7. In Example 2, the combination tablets (Formulations 3 and 4) were prepared differently to Formulations 1 and 2. In Formulation 3, entacapone and levodopa, with certain excipients, were wet granulated together. Carbidopa was wet granulated, with certain excipients, separately. The entacapone/levodopa granules (and excipients) and the carbidopa granules (and excipients) were mixed together and compressed into tablets which were then coated. Formulation 4 was prepared analogously, except that carbidopa was added in a powder form. The excipients used in Formulations 3 and 4 were different to the excipients used in Formulations 1 and 2.
8. The blood plasma levels of entacapone (Figure 4), levodopa (Figure 5) and carbidopa (Figure 6) respectively were measured after Formulation 3, Formulation 4 and the reference products were administered to the volunteers. The results showed that Formulation 3 and Formulation 4 were comparable with the reference products, in terms of absorption of the active agents.
9. In Example 3, two formulations (Formulations 5 and 6) were prepared according to the procedure used for Formulation 3, but using different amounts of entacapone, levodopa and carbidopa. The core tablets were then coated.
10. In giving a detailed description of the invention, the specification states   
    (at page 7, lines 1-12):

Applicants have surprisingly discovered that an oral solid composition enabling sufficient absorption of active agents can be achieved by combining entacapone, levodopa and carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, in a single formulation. This has been achieved, inter alia, by improving the bioavailability and the stability of the composition, and improving the method for preparing the composition.

Applicants have found that absorptions of levodopa, carbidopa and entacapone from the digestive tract are highly variable. The bioavailabilities of levodopa and carbidopa vary both intra- and interindividually. The bioavailability of entacapone has also been extensively studied by the Applicant to arrive at the present invention.

1. The appellants place particular reliance on the last sentence of the first paragraph quoted above.
2. The specification continues by referring to the fact that “[i]t is very challenging to harmonize the absorptions of three active ingredients from one and the same oral solid composition” and that “the method for preparing the composition has a significant effect on the bioavailability of carbidopa”: page 7, lines 13-16. Here, the specification refers to the low bioavailability of carbidopa in Formulation 1 compared to the levodopa/carbidopa reference product, and the stability problems caused by the use of polyethylene glycol in Formulation 2.
3. The specification then says that “a preferred way to increase the bioavailability of carbidopa from an oral solid composition comprising entacapone, levodopa and carbidopa”   
   (page 8, lines 3-5) has been found—namely, to mix levodopa and entacapone together and then add carbidopa, separately, to this mixture.
4. The specification continues (at page 8, lines 7-10):

The invention therefore provides an oral solid composition of entacapone, levodopa, and carbidopa, or pharmaceutically acceptable salts or hydrates thereof, and a pharmaceutically acceptable excipient, wherein a substantial portion of carbidopa is separated from entacapone and levodopa.

1. This is the consistory statement for claim 1 of the patent.
2. The specification states, in general terms, how such a composition can be obtained:   
   page 8, lines 11-16. It then describes a process for preparing an oral solid composition of the invention which stands as the consistory statement for claims 12 and 13 of the patent:   
   page 8, lines 17-23. The specification says that examples of “these kinds of formulations according to the invention” are described in Example 2: page 9, lines 10-11.
3. The detailed description then turns to discuss the compatibility of the ingredients of compositions of the invention. The specification discloses that entacapone, levodopa and carbidopa are compatible with each other, but many commonly used excipients are not suitable to be used in compositions containing these active agents. The specification says that most available levodopa/carbidopa formulations available in the market contain MCC and that certain recent formulations of entacapone (such as those used in the entacapone reference product) contain considerable amounts of MCC. The specification says that, for compounds of the invention, it was unexpectedly found that MCC destabilises the formulations on long term storage. The specification states (at page 10, lines 6-10):

Accordingly, the invention provides a stable oral solid pharmaceutical composition comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or pharmaceutically acceptable salts or hydrates thereof, and at least one pharmaceutically acceptable excipient other than microcrystalline cellulose.

1. This is the consistory statement for claim 11 of the patent.
2. Additionally, the specification discloses that polyethylene glycol as an excipient resulted in tablets that were found to be unstable in a standard stability test: see [30] above. It also discloses (at page 10, lines 11-21) that other surface-active substances (for example, polysorbate and sodium lauryl sulphate) have been found to be incompatible with the fixed dose composition, as have colloidal silicone oxide and copolyvidone.
3. The specification then says (at page 10, line 22 to page 11, line 4):

Accordingly, as a preferred embodiment of the invention, a stable oral solid pharmaceutical composition is provided comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or a pharmaceutically acceptable salt of hydrate thereof, and at least one pharmaceutically acceptable excipient other than microcrystalline cellulose and/or surface active agents and/or silica.

1. The specification also says that, despite the several incompatibilities found, “the oral solid composition according to the invention can still surprisingly be prepared by using few compatible excipients alone or two or more together”: page 11, lines 5-7. The specification gives sugar alcohols (preferably, mannitol) and starch (preferably, maize starch) as appropriate excipients to be used.
2. The specification continues (at page 11, lines 10-14):

Accordingly, the present invention provides an oral solid composition comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, and comprising at least one pharmaceutically acceptable excipient being a sugar alcohol, starch or sugar alcohol and starch.

1. This is the consistory statement for claim 4 of the patent.
2. After discussing other suitable excipients, disintegrants and binders, the detailed description turns to consider the amounts of entacapone, levodopa and carbidopa to be used in the composition. These amounts are said to be known to one skilled in the art. The specification also says that other pharmacologically active agents can be used, additionally, in the composition. The specification gives embodiments containing dosages of the three active agents that are “particularly preferred”: page 13, lines 3-11.
3. The specification continues (at page 13, lines 12-21):

As a further aspect the invention provides an oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, and comprising at least one pharmaceutically acceptable excipient, whereby the therapeutic effect achieved with the said composition in the treatment of Parkinson’s disease is comparable, e.g. similar, to that achieved with the known separate formulations of entacapone, levodopa and carbidopa, e.g. entacapone tablets and levodopa-carbidopa tablets referred to herein, which are administered concomitantly, at the same doses of the active agents as the combination formulation of the invention.

1. This is the consistory statement for claim 21 of the patent.
2. After describing certain other embodiments of the invention, which are said to be pharmacokinetically comparable to the known separate formulations of entacapone and levodopa/carbidopa at the same doses, the detailed description turns to consider the question of tablet size.
3. Here, the specification discloses that compaction granulation is used for entacapone tablets. The specification says that compaction granulation requires large amounts of excipients to be used in order to obtain the desired fast dissolution behaviour of an immediate release formula. But, notwithstanding these large amounts of excipients, a 200 mg tablet can be prepared which, the specification says, is relatively easy to swallow. The specification says that the compactability of the fixed dose combination tablets of the invention was found to be surprisingly worse than for entacapone tablets alone and that these tablets can become too large, especially for parkinsonism patients who have difficulties in swallowing. Polyethylene glycol was found to be a useful compression aid that improved compactability but, as stated above, this excipient was found to produce tablets that were unstable in storage:   
   page 15, line 19 to page 20, line 9.
4. The specification then describes the following process (at page 16, lines 10-23):

The invention thus provides an advantageous process for preparing an oral solid composition of the invention, wherein the method comprises a) mixing pharmacologically effective amounts of entacapone and levodopa, or a pharmaceutically acceptable salt or hydrate thereof, with at least one pharmaceutically acceptable excipient and optionally a disintegrant to obtain a first mixture; b) granulating the first mixture to obtain a first granule batch; c) mixing a pharmacologically effective amount of carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, with at least one pharmaceutically acceptable excipient and optionally a disintegrant to obtain a second mixture; d) granulating the second mixture to obtain a second granule batch; e) mixing the first granule batch, the second granule batch, optionally a lubricant, and optionally one or more pharmaceutically acceptable excipients, to obtain a third mixture; f) formulating the third mixture to a plurality of dosage forms, e.g. compressing the third mixture into a plurality of tablets and optionally coating the tablets.

1. This is the consistory statement for claim 16.
2. A further process is described (at page 17, lines 1-11):

An oral solid composition according to the invention can also be prepared by a) mixing pharmacologically effective amounts of entacapone and levodopa, or a pharmaceutically acceptable salt or hydrate thereof, with at least one pharmaceutically acceptable excipient and optionally a disintegrant to obtain a first mixture; b) granulating the first mixture to obtain a plurality of granules; c) adding a pharmacologically effective amount of carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, optionally a lubricant and optionally one or more pharmaceutically acceptable excipients, to the granules to obtain a second mixture; d) formulating the second mixture to a plurality of dosage forms, e.g. compressing the second mixture into a plurality of tablets and optionally coating the tablets.

1. This is the consistory statement for claim 17.
2. The specification says that, by using the process of the invention, tablet compositions of the invention may be made which, for the dosages contained therein, are particularly small and convenient to administer: page 17, lines 18-20.
3. The specification discloses a particular oral pharmaceutical tablet (at page 18, lines 4-9):

In another aspect the present invention provides an oral pharmaceutical tablet comprising 200mg entacapone, 50-150mg levodopa, and 10-37.5 mg carbidopa and having preferably substantially the following characteristics:

weight 400-750 mg, e.g. 550-590 mg,

volume dimensions for oval tablet preferably from 200 to 1000 mm3,   
e.g. 250 to 800 mm3, such as 300 to 600 mm3, e.g. 300 to 550 mm3.

1. This is the consistory statement for claim 19.
2. The specification discloses another oral pharmaceutical tablet (at page 18, lines 10-17):

In yet a further aspect the present invention provides an oral pharmaceutical tablet comprising 200mg entacapone, 50-150mg levodopa, and 10-37.5 mg carbidopa and having substantially the following characteristics:

weight 400-750 mg, e.g. 550-590 mg,

volume dimensions for oval tablet preferably,

length 13-18 mm, e.g. 14-18 mm,

width 6-9 mm,

height 4-7 mm, e.g. 5-6 mm.

1. This is the consistory statement for claim 20.
2. The specification proceeds to discuss the Examples to which we have referred at [30]-[33] above.
3. Following these Examples, the specification states (at page 24, line 23 to page 25, line 2):

Those skilled in the art will recognize that while specific embodiments have been illustrated and described, various modifications and changes may be made without departing from the spirit and scope of the invention.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

1. The specification also provides the following explanation (at page 25, lines 3-5):

Throughout the description and claims of the specification the word “comprise” and variations of the word, such as “comprising” and “comprises”, is not intended to exclude other additives, components, integers or steps.

1. As we will come to explain, the scope to be given to “comprise” and its variants, so as not to exclude other additives, components, integers or steps, assumed considerable importance for the primary judge’s construction of the claims in suit, particularly in relation to claim 17.
2. The specification ends with 24 claims.
3. Relevantly, claim 17 is directed to a method of preparing an oral solid composition comprising entacapone, levodopa and carbidopa. Claims 19 and 20 are directed to particular oral pharmaceutical tablets comprising entacapone, levodopa and carbidopa. Claim 21 is directed to an oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa. We will refer in more detail to these claims when summarising the primary judge’s findings that are relevant to this appeal.

# The primary judge’s reasons

## The definition of the invention issue

1. Relevantly to this appeal, the primary judge dealt, firstly, with what he described as **the definition of the invention issue**. His Honour noted that this issue concerns a number of claims, including claims 17, 18 and 21. His Honour posed the question whether any of these claims are invalid because they fail to define the invention?
2. Notwithstanding his Honour’s question, the issue here is not really one of claim definition, but whether each of the challenged claims is fairly based on the matter described in the specification, as required by s 40(3) of the Act (in the form it took before the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth))—a matter which the primary judge subsequently considered at [161]-[182]: see [102]-[112] below. Nonetheless, in order to consider the question of fair basis, it is necessary to identify and understand “the matter described in the specification”. This, then, is the issue to which the definition of the invention issue is directed.
3. Before the primary judge, the appellants focused on the passage we have quoted at [19] above—in particular, that part which says that “a composition according to the invention” has, amongst other things, “preferable stability and bioavailability characteristics and which is easy to swallow”—and the passage we have quoted at [34] above, which speaks of the “single formulation” as having been achieved by “improving the bioavailability and the stability of the composition, and improving the method for preparing the composition”.
4. The primary judge at [68]-[69] summarised the appellants’ submission as follows:

68 Actavis submitted that, read as a whole, the specification repeatedly characterised the invention by reference to the characteristics of stability, bioavailability and tablet sizes appropriate for administration to patients suffering from Parkinson’s disease, being persons who are known to have potential difficulties in swallowing. It argued that the skilled addressee would know that a tablet containing a composition of the three APIs would have to achieve at least equivalent bioavailability to the existing separate formulations of entacapone and a composition containing levodopa and carbidopa.

69 It also relied on the description on page 7 par 1 … and other references in the body of the specification to bioavailability, absorption of the APIs and stability as critical indicia of the invention. Actavis argued that the specification made clear that the patentee did not consider formulations 1 and 2 to be within the invention claimed. That was because, Actavis contended, the specification taught that the bioavailability of carbidopa from formulation 1 was “too low” and the use of polyethylene glycol in formulation 2 caused stability problems, whereas the specification’s teaching on formulations 3 and 4 was not so qualified, and on formulations 5 and 6 was that these were examples of “suitable” formulations of the three APIs.

1. The primary judge rejected the appellants’ characterisation of the invention as one requiring particular or specific characteristics relating to stability, bioavailability and ease of swallowing. At [71], the primary judge said:

I am of the opinion that the invention described in the complete specification was, *first*, a product, being an oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa and at least one pharmaceutically acceptable excipient, *secondly*, a process or method for preparing that product and, *thirdly*, a method of using it. In short, the patent identified a new three-in-one combination (tablet) that provided an oral fixed dose of pharmacologically effective amounts of the three [active agents] with at least one pharmaceutically acceptable excipient and methods to produce and use that combination product.

(Emphasis in original.)

1. His Honour held at [72]-[73] that the three characteristics on which the appellants relied represented the consequences of preferred embodiments, and would be understood as such by the person skilled in the art. His Honour noted that the specification teaches that the prior art had not described an oral solid composition comprising entacapone, levodopa and carbidopa and had defined “a composition according to the invention” as “…an oral solid fixed dose composition comprising pharmacologically effective” amounts of entacapone, levodopa and carbidopa and at least one pharmaceutically acceptable excipient.
2. His Honour reasoned at [74] that it would be unusual for a patentee to define an invention as limited to preferred embodiments. His Honour said at [75] that the specification does not prescribe particular stability or bioavailability characteristics to limit or further define the invention, beyond the preferred embodiment reflected in claim 21. Similarly, other than for claim 21, the claims do not define the integers of the invention by reference to stability, bioavailability or therapeutic criteria or results.
3. His Honour said at [75] that the preferred embodiments reflected in claims 19 and 20 are of tablets with ranges of ingredients, volumes and dimensions that will be understood by the person skilled in the art as conformable with the manufacture of tablets that are sufficiently small as to be easy for sufferers of Parkinson’s disease to swallow.
4. Finally, at [76] his Honour said that the appellants’ characterisation of the invention was driven with an eye to avoiding the consequences of infringement: *GlaxoSmithKline Australia Pty Ltd v Reckitt Benckiser Healthcare (UK) Ltd* (2013) 305 ALR 363; [2013] FCAFC 102 at [60].

## The construction issue

1. Secondly, the primary judge dealt with what he described as **the construction issue** which included certain questions of construction affecting claims 17, 19, 20 and 21, amongst other claims.

### Claim 17

1. Claim 17 is:

A method for preparing an oral solid composition comprising entacapone, levodopa, and carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, wherein the method comprises

1. mixing pharmacologically effective amounts of entacapone and levodopa, or a pharmaceutically acceptable salt or hydrate thereof, with at least one pharmaceutically acceptable excipient and a disintegrant to obtain a first mixture;
2. granulating the first mixture to obtain a granule batch;
3. adding a pharmacologically effective amount of carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, optionally a lubricant, and optionally one or more pharmaceutically acceptable excipients to the granule batch to obtain a second mixture;
4. formulating the second mixture into a plurality of dosage forms.
5. One question of construction considered by the primary judge in respect of this claim is the meaning to be given to the words “pharmacologically effective amount” of carbidopa, as used in step c). At [111], the primary judge held that the person skilled in the art would understand these words to convey “the meaning of an amount of the relevant [active agent] that ordinarily is known to be capable of producing a desired beneficial effect in the treatment of patients suffering Parkinson’s disease”.
6. Another question of construction concerns step a). This step refers to mixing pharmacologically effective amounts of entacapone and levodopa to obtain a first mixture to which, in step c), a pharmacologically effective amount of carbidopa is added. The primary judge reasoned at [114] and [117] that the amount of levodopa added in step a) could be a low, but nevertheless pharmacologically effective, dose and that a further amount of levodopa could be added in a later step, including in step c), provided that the addition, at the later step, does not compromise the pharmacological effectiveness of the overall composition. At [114], his Honour gave the following illustration of how the method of claim 17 could be performed:

… the amount of levodopa added in step a) in claim 17 could be the lowest in the particularly preferred range described in the patent (page 13), namely 50 mg. That is a pharmacologically effective dose of levodopa. That 50 mg would be added with the 200 mg of entacapone in the first mixture, but a further 50 mg of levodopa could be added later to take the total dose to 100 mg, also a pharmacologically effective amount.

1. At [115], his Honour said that step a) does not require the whole amount of the intended dose of entacapone and levodopa to be added at that point.
2. In this connection, the primary judge drew a distinction between the drafting of claim 17 and other claims. At [116], his Honour said:

Unlike claims 1, 2, 12, 13 and 14, claim 17 does not require specifically that all, or a substantial portion of, carbidopa be separate, or added separately from, the other two APIs. Clearly enough, step c) requires that carbidopa be added after the creation of the first mixture. But, the word “comprises” in the chapeau of claim 17 can be given the wide meaning of its definition in this claim that would permit the addition, at step c), of “other additives [or] components” (page 25). The word “comprises”, as used in claim 17, qualifies the whole of the balance of the claim in steps a) - d).

### Claims 19 and 20

1. Claim 19 is:

An oral pharmaceutical tablet comprising 200mg entacapone, 50-150mg levodopa, and 10-37.5 mg carbidopa and having substantially the following characteristics:

weight 400-750 mg, and volume dimensions for tablet from 200 to 1000 mm3.

1. Claim 20 is:

An oral pharmaceutical tablet comprising 200mg entacapone, 50-150mg levodopa, and 10-37.5 mg carbidopa and having substantially the following characteristics:

weight 400-750 mg; and volume dimensions for tablet:

length 13-18 mm; width 6-9 mm; and height 4-7 mm.

1. Before the primary judge, the appellants submitted that claims 19 and 20 are not limited to tablets prepared using the process of the invention disclosed in the specification which, according to the appellants, requires the carbidopa to be added separately to a mixture of entacapone and levodopa. This submission appears to have been a step in the appellants’ case that claims 19 and 20 are not fairly based on the matter described in the specification, contrary to s 40(3) of the Act.
2. At [122]-[124], the primary judge rejected the appellants’ submission. In doing so, his Honour appears to have focused on the stability of the tablets rather than the question of whether the tablets were prepared from a composition in which carbidopa was added separately to entacapone and levodopa. His Honour reasoned that the word “pharmaceutical”, as used in claims 19 and 20, necessarily implies that the three active agents would be used with excipients; that the expression “an oral pharmaceutical tablet”, as used in the claims, conveys the meaning of a tablet suitable for oral administration as a medicine in the treatment of Parkinson’s disease; and that the persons skilled in the art would understand the word “pharmaceutical” to be used in the claims to “convey that such a tablet must have sufficient stability and be composed of such additional ingredients that it would be of a standard and quality that is suitable to be approved by regulatory authorities for administration to patients as a treatment for Parkinson’s disease”.

### Claim 21

1. Claim 21 is:

An oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa, and carbidopa, or pharmaceutically acceptable salts or hydrates thereof, and comprising at least one pharmaceutically acceptable excipient, whereby the therapeutical effect achieved with the said composition in the treatment of Parkinson’s disease is comparable to that achieved with the known separate formulations of entacapone and levodopa and carbidopa which are administered concomitantly at the same doses of the active agents as the present combination formulation.

1. There is no issue that the word “therapeutical”, as used in this claim, should be understood as “therapeutic”.
2. Before the primary judge, the appellants argued that the integer of comparability of the therapeutic effect is vague and uncertain. His Honour rejected that submission.   
   At [127]-[128], his Honour said:

127 I am of opinion that the skilled addressee would understand that the comparison identified in claim 21 will be between the overall therapeutic effect achieved by each of the three APIs as a result of the two means of delivery, namely, the claimed solid oral fixed dose composition of the three APIs on the one hand and, on the other, the concurrent administration of the known means, being separate formulations of, *first*, entacapone and, *secondly*, the combination of levodopa and carbidopa.

128 A skilled addressee would understand that the comparison called for by claim 21 was of the respective efficacy of the three-in-one combination, to achieve a similar amount of levodopa crossing the blood brain barrier as occurred by use of the existing reference products with similar administered amounts of the three APIs.

(Emphasis in original.)

1. His Honour said that the absence of a precise scale or measure in claim 21 does not render the claim unclear. The assessment of comparability will involve a question of fact and degree. At [130], his Honour found that:

The assessment of comparability in respect of claim 21 in any case will involve a question of fact and degree, but, in the present context, I do not think that it gives rise to any ambiguity: *Monsanto* 48 ALJR at 60; *Minnesota* 144 CLR at 286. The skilled addressee would have little difficulty in assessing whether a particular composition of pharmacologically effective amounts of the three APIs achieves a comparable effect to that of the known formulations at the priority date of 200 mg of entacapone and any one of the combinations of levodopa and carbidopa (including fractional dosages that the manufacturers of those tablets allowed to occur and clinicians prescribed), in effecting the ultimate healing or curative purpose of delivering a sufficient amount of levodopa past the blood brain barrier. Ordinarily, such a comparison can be made by considering the respective bioavailability of each API in the two forms of administration being considered.

1. At [131]-[135], his Honour rejected an argument which he attributed to one of the appellants’ witnesses, Dr Phillip Reece, that the comparison required by claim 21 involves the use of Figures 1 to 6 in the specification. At [135], his Honour found that the requirement of comparability in claim 21 involves:

… an objective comparison of the pharmacokinetics, including bioavailability (tested by reference to standard methods of using maximum concentration (C max) and area under curve (AUC) measures of blood plasma levels over time), of each of the three APIs in the composition said to fall within claim 21 as against those of the reference products.

## The infringement issue

1. Thirdly, the primary judge dealt with the question of infringement of the claims in suit (**the infringement issue**). As we have noted, his Honour found that the appellants had threatened to infringe claims 17, 18, 19, 20 and 21 of the patent.

### Claim 17

1. Before the primary judge, the appellants argued that the process of manufacture used for the Actavis products (**the Actavis process**) is not the process claimed in claim 17.
2. XXX XXX XXX X XX XX XXXX XXXXX XX XXXXXXX XXXXXXXXX XXXXXXX XXX XXX XXXXXX XXXX XXX XXXX XXX XXXXX XXX XX XXXXX XXXXX XXXXXX XX XX XXXXXX XXXXX XXXX XXXX XXX XXX XXX X XX XX XXXX XXXXX XX XXXXXXX XXXXXXXXX XXXXXXX XXX XXX XXXXXX XXXX XXX XXXX XXX XXXXX XXX XX XXXXX XXXXX XXXXXX XX XX XXXXXX XXXXX XXXXXXXXXXXX XXXXXXXXXXXXX XXXXXXXXXXXX XXXXXXXXX
3. XXX XXX XXX X XX XX XXXX XXXXX XX XXXXXXX XXXXXXXXX XXXXXXX XXX XXX XXXXXX XXXX XXX XXXX XXX XXXXX XXX XX XXXXX XXXXX XXXXXX XX XX XXXXXX XXXXX XXXX XXXX XXX XXX XXX X XX XX XXXX XXXXX XX XXXXXXX XXXXXXXXX XXXXXXX XXX XXX XXXXXX XXXX XXX XXXX XXX XXXXX XXX XX XXXXX XXXXX XXXXXX XX XX XXXXXX XXXXX XXXXXXXXXXXX XXXXXXXXXXXXX XXXXXXXXXXXX XXXXXXXXX X XXXX XXX XXXX XXX XXXXX XXX XX XXXXX XXXXX XXXXXX XX XX XXXXXX XXXXX XXXXXXXXXXXX XXXXXXXXXXXXX XXXXXXXXXXXX X XXXXXXXX X

### Claim 18

1. Claim 18 is dependent on claims 16 and 17. It adds the feature that the granulation method is wet granulation. At [148], the primary judge was satisfied that this additional feature is also present in the Actavis process.

### Claims 19 and 20

1. At [149], the primary judge recorded that the appellants had accepted that five of the six Actavis products infringe claims 19 and 20, based on the construction his Honour had given to those claims (see [83]-[86] above). His Honour noted that it was common ground that the sixth product does not infringe these claims because the doses of levodopa and carbidopa in that product exceed the corresponding maximum doses for levodopa and carbidopa specified in these claims.

### Claim 21

1. At [150], the primary judge recorded the appellants’ acceptance that all the Actavis products infringe claim 21 if that claim is to be given the construction found by his Honour, as summarised at [87]-[91] above.

## The clarity issue

1. Fourthly, the primary judge turned to consider the question of whether certain claims, including claims 17, 18 and 21, are invalid because they are not clear (**the clarity issue**).
2. Relevantly to this appeal, the appellants argued that the use of the words “comprising” and “comprises” in claims 17 and 18 renders the claims unclear or ambiguous. Before the primary judge, the appellants argued that these words could not justify a construction that “did not respect the distinction or separation that each claim require[s] for carbidopa, or a substantial portion of [carbidopa], from [entacapone and levodopa]”. At [159], the primary judge found that, based on his construction of claims 17 and 18, they do not lack clarity or become ambiguous.
3. With respect to claim 21, the appellants submitted that the standard of comparability referred to lacks clarity. They argued that what constitutes a “comparable” therapeutic effect is unclear because no precise standard has been given in claim 21 against which the comparison can be evaluated. The appellants submitted that claim 21 requires the person skilled in the art to make a subjective judgment as to comparability. At [160], the primary judge rejected this submission, based on his Honour’s construction discussed at [87]-[91] above.

## The fair basis issue

1. Fifthly, the primary judge turned to consider whether a number of claims of the patent, including claims 17, 18, 19, 20 and 21, are fairly based on the matter described in the specification (**the fair basis issue**). His Honour noted that the principal basis of the appellants’ attack in this regard was the identification of the invention. At [161], the primary judge encapsulated the appellants’ submission, as follows:

Actavis argued that claims 1, 2, 12, 13, 14, 17, 18, 19, 20 and 21   
(**the challenged claims**) were not fairly based on the matter described in the specification. The principal basis of Actavis’ attack was its identification of the definition of the invention that I have rejected at [72]-[76] above. In essence, it argued that the body of the specification as a whole disclosed the invention as encompassing particular or specific characteristics relating to stability, bioavailability and ease of swallowing and that these characteristics were achieved by a particular process for preparing the composition. Actavis also submitted that the process described in the specification included, *first*, both the use of certain compatible excipients and excluded certain incompatible ones so as to achieve stability, and, *secondly*, the method of mixing entacapone and levodopa separately and then adding carbidopa so as to result in the separation of a substantial portion of carbidopa from the other two APIs in order to achieve bioavailability and ease of swallowing.

(Emphasis in original.)

1. The appellants argued that each challenged claim is not fairly based because it does not exclude incompatible excipients, namely MCC as well as the excipients referred to at pages 10 to 11 of the specification.
2. Further, the appellants submitted that certain claims, including claims 17 and 18, if construed to permit the mixing of carbidopa with either levodopa or entacapone, are not described in the specification and that the mere making of the consistory statement for claim 17 is insufficient to support those claims.
3. The appellants advanced a similar argument with respect to claims 19, 20 and 21. They submitted that these claims do not refer to the separation, or separate addition, of carbidopa or the need to exclude incompatible excipients.
4. The appellants also argued that claims 19 and 20 travel beyond the matter described in the specification because such tablets could be made by any method. Further, the appellants submitted that claim 21 is not fairly based because it is not limited to compositions prepared by the method described in Formulations 3 and 4.
5. The primary judge rejected all these arguments.
6. With respect to incompatible excipients, the primary judge noted at [171] that the specification does not describe MCC as an unacceptable excipient “except in the one circumstance in which [entacapone, levodopa and carbidopa] were combined together”. His Honour said that claim 11 reflected this exclusion. His Honour found that the specification does not suggest that MCC is unsuitable if carbidopa is added separately to entacapone and levodopa, and the three “were not all combined together”. His Honour also said that the specification describes the exclusion of MCC, and other excipients, as a preferred embodiment, and not as an essential feature of the invention.
7. At [172], the primary judge found that the only description of a process in which tablets comprising MCC and polyethylene glycol were found to be unstable was in respect of Formulation 2. However, Formulation 2 also comprised granules in which the three active agents were compaction granulated together.
8. At [174]-[175], the primary judge held:

174 None of the challenged claims required the exclusion of particular excipients. The fact that some excipients might cause a composition not to meet standard stability tests did not necessarily entail, and there was no evidence to suggest that it did entail, that a composition of the three APIs that included any such excipient would not work at all. The achievement of particular stability over time in standard conditions is a desirable result for commercial drug manufacture. However, the mere failure of a product to achieve that level of stability because it includes a particular ingredient does not necessarily mean that a patent claim that can include the ingredient is not fairly based on a specification that discloses the problem of achieving the desired stability.

175 Such a situation does not establish that, despite the combination’s tenuous longevity, it does not work as claimed before it deteriorates. And a preferred embodiment that excludes the ingredient, and so achieves the requisite stability, can also be within the claim. The former, less stable, embodiment merely did not work as well, or for as long, as the preferred one. Actavis did not prove, and the specification did not teach, that the inclusion of MCC, surfaceactive [sic] substances or silica in the combination affected anything other than the resultant product’s longer term stability.

1. The primary judge discussed certain aspects of the expert evidence concerning the need to establish sufficient stability of a drug to be used in clinical trials. He noted that the stability studies discussed in the specification reveal that MCC, surface active agents and silica had the potential to affect the stability of a three-in-one composition of entacapone, levodopa and carbidopa in the longer term. At [178] his Honour found:

Importantly, the inclusion of any of those excipients did not, on the evidence, preclude a composition containing it and the three APIs from delivering an intended dosage of levodopa past the blood brain barrier, if it were administered before the time that the effect of the relevant excipient’s inclusion on the longer term stability of the product had caused it to deteriorate so that it would not deliver that intended dose.

1. With respect to claim 21, the primary judge found that the appellants’ argument (that the claim to the composition is not fairly based because the method of preparation of the composition is not limited to the method used for Formulations 3 and 4) was flawed. At [181], the primary judge reasoned that the specification puts forward Formulations 3 and 4 as examples of embodiments that achieve therapeutic effects comparable to the reference products. His Honour pointed to the passages we have quoted at [63] above and found that it was not possible to discern any limitation of the kind suggested by the appellants, that would render claim 21 invalid as not complying with s 40(3) of the Act. At [182], his Honour said:

… Claim 21 was fairly based because it created a limitation of the monopoly by identifying a requirement of comparability of therapeutic effect for the new   
[three]-in-one combination tablet with that achieved by the existing products.

## Other matters

1. The primary judge went on to consider other challenges to validity (namely, inutility, lack of novelty and lack of inventive step). His Honour was not satisfied that these challenges were made out. It is not necessary for us to discuss his Honour’s reasons because his findings and conclusions in that regard are not challenged in this appeal.
2. As we have noted (at [7]) above, the primary judge considered the legal effect of the   
   2014 licence and 2014 sub-licence in Reasons 3. We will deal with those reasons separately.

# An overview of the appeal

1. At the commencement of the hearing of the appeal, the appellants were granted leave to file a further amended notice of appeal (**the notice of appeal**), the effect of which was to remove certain previously pleaded grounds of appeal and to elaborate on others. The notice of appeal contains 16 grounds. Helpfully, the appellants distilled these grounds into four principal contentions.
2. First, the appellants contend that the primary judge misinterpreted the invention described in the specification and erroneously found that claims 17 to 22 are fairly based: Grounds 1, 2, 12 and 13.
3. Secondly, the appellants contend that the primary judge misconstrued claim 17 and erroneously found that the Actavis products infringe claim 17 and dependent claim 18: Grounds 3 and 6. Alternatively, the appellants contend that, if the primary judge’s construction of claim 17 is correct, then claims 17 and 18 are not fairly based and lack clarity and/or definition: Grounds 10 and 13.
4. Thirdly, the appellants contend that the primary judge erred in not finding that claims 17 and 21, and dependent claim 22, lack clarity and/or definition: Grounds 3, 5, 10 and 11.
5. Fourthly, the appellants contend that the primary judge erred in finding that Novartis and Novartis Australia have standing to sue for infringement: Grounds 14, 15, and 16.
6. As will become apparent from the discussion below, there are permutations of the four principal contentions, which are reflected in other grounds of appeal. We will deal with those permutations as they arise in respect of each principal contention.

# The first contention: fair basis

## The appellants’ submissions

1. The appellants contend that claims 17 to 22 are not fairly based because, in each case, the invention as claimed is not limited to require use of a method that:

* separates carbidopa from levodopa and entacapone (so as to produce a composition in which a *substantial* portion of carbidopa is separated from levodopa and entacapone); and
* excludes use of the incompatible excipients identified in the specification.

1. By way of general overview, the appellants submit that the specification describes the invention as an oral composition and a method of making an effective oral composition that combines the three active agents in a manner that solves three identified problems. The first problem is that when carbidopa is mixed with levodopa and entacapone, the bioavailability of carbidopa is too low compared with the reference products (**the bioavailability problem**). The appellants say that this was solved by use of the method in which a substantial portion of carbidopa is separated from levodopa and entacapone. The second problem is that when certain common excipients are used in compositions containing the three active agents, incompatibilities lead to instability of the resulting product (**the stability problem**). The appellants say this this was solved by avoiding these excipients and using only compatible excipients for the three-in-one composition. The third problem is to manufacture a   
   three-in-one composition in the form of a tablet that is easy to swallow (**the size problem**). The appellants say this was solved by the solution to the bioavailability problem.
2. As we have noted, the appellants place particular significance on the statement in the summary of the invention that the composition has “preferable stability and bioavailability characteristics and which is easy to swallow” (at page 3, lines 13-21, quoted at [19] above) and submit that, contrary to the primary judge’s understanding, these words serve to identify that a standard of stability, bioavailability and size is required. The appellants submit that these characteristics are described in greater detail in later passages of the specification   
   (see at [124] below) and that the primary judge erred in concluding that embodiments possessing these features are no more than preferred embodiments. In this connection, the appellants draw attention to the fact that the summary describes the invention as having “preferable” stability and bioavailability characteristics; by way of contrast, the appellants emphasise that the specification does not say that, “preferably”, the invention has these characteristics. Thus, the appellants submit, the primary judge erred by reading down the invention that the specification describes. We take this submission to mean that the primary judge erred by finding that, as described in the specification, the invention is more broadly based than that for which the appellants contend.
3. In this connection, the appellants submit that the true scope of the invention is reflected in the following passages of the specification:

* the description of the background to the invention, which states that patient compliance with parkinsonism medication can be improved by using a fixed dose combination of the three active agents but identifies (a) the problem that it is very difficult to adjust the absorption of three different active agents from one and the same oral solid composition, and (b) the need to consider numerous factors (including the bioavailabilities of the active agents and the stability of the composition) in selecting the pharmaceutical excipients, disintegrants and other auxiliary agents to be used in an pharmaceutical composition which combines several active agents: see [18] above;
* the description of the summary of the invention, which includes the statements quoted at [19] above; the statements about particular excipients that can be used, including those referred to at [22]-[23] above; and the statement quoted at [24] above concerning the particularly interesting way to increase the bioavailability of carbidopa from the three-in-one composition; and
* the detailed description of the invention, which includes the statements quoted   
  at [34] above concerning the surprising discovery of an oral solid composition that combines entacapone, levodopa and carbidopa which enables sufficient absorption of the active agents and the fact that this combination has been achieved by improving the bioavailability and stability of the composition, amongst other things; the statement referred to at [36] above concerning the challenge of harmonising the absorptions of the three active agents from one and the same oral solid composition; the statements concerning the preferred way of increasing the bioavailability of carbidopa from the three-in-one composition referred to at [37] and quoted at [38] above; the statements referred to at [40] above about how the separation of carbidopa from entacapone and levodopa in the three-in-one composition can be achieved; the statements referred to at [41]-[46] above concerning the compatibility of ingredients used in the composition; and the statements referred to a [51]-[57] concerning tablet size, in particular the statement that, by using the process of the invention, tablet compositions can be made which are particularly small for the dosages contained therein and which are convenient to administer.

1. The appellants challenge a number of aspects of the primary judge’s reasoning.
2. First, the appellants direct attention to the primary judge’s observation at [75] that it is “notable” that the specification does not “prescribe particular stability or bioavailability characteristics to limit or further define the invention”, beyond the description of the preferred embodiment claimed in claim 21 (see [74] above). The appellants argue that the primary judge’s observation is inapposite because the specification teaches how the desired bioavailability and stability of the three-in-one composition can be achieved: the desired bioavailability can be achieved by mixing levodopa and entacapone together and then adding carbidopa; the desired stability can be achieved by not using the excipients identified in the specification as being “not suitable”.
3. The appellants also criticise the primary judge’s related observation at [75] that the claims (themselves part of the specification), other than claim 21, do not *define* the invention by reference to stability, bioavailability or therapeutic criteria or results. The appellants submit that his Honour’s observation in this regard impermissibly seeks to import, for the purposes of s 40(3) of the Act, the language of the claims into “the matter described in the specification” to which the claims are to be compared. Further, the appellants submit that his Honour’s related observation seeks to make a virtue out of the very deficiencies which give rise to the lack of fair basis of which they complain.
4. Secondly, the appellants direct attention to the primary judge’s observation (at [174]-[175]) that, although some excipients might cause a three-in-one composition not to meet standard stability tests, it does not follow that such a composition will not work at all. Here, the appellants submit that, by pursuing an enquiry as to what *could* work (in terms of conferring a therapeutic benefit), the primary judge was distracted from pursuing the relevant s 40(3) enquiry, which is what the specification, read as a whole, describes as the invention. The appellants argue that a specification is not to be read as going beyond the inventor’s own endeavours as stated in the specification: *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2011] AIPC 92-428; [2011] FCAFC 132 at [242]. The appellants submit that, when the specification is properly understood, it does not describe the invention as residing in an unstable composition, even though the primary judge considered possible uses of a composition of “tenuous longevity” before it “deteriorates”.
5. Thirdly, the appellants submit that, although there are “matching” statements in the specification for each of claims 17 and 19 to 21, the invention which is described “is narrower and more confined than the scope of” each of these claims. The appellants submit that a claim based on a consistory statement will not be fairly based if other parts of the matter described in the specification show that the invention is narrower than that consistory statement: *Lockwood Security Products Pty Limited v Doric Products Pty Limited* (2004) 217 CLR 274; [2004] HCA 58 (***Lockwood***) at [99].
6. The appellants raise additional problems with respect to the primary judge’s findings in relation to claims 19 and 20, which are expressed in Grounds 4 and 7 of the notice of appeal.
7. In this connection, the appellants say that, on their face, and as accepted by the parties and the experts, claims 19 and 20:

* do not require that a substantial portion of carbidopa be separated from levodopa and entacapone in the three-in-one composition; and
* do not exclude incompatible excipients.

1. The appellants say that the primary judge reached the same conclusion at [164] and at [174] when dealing with the fair basis issue, but reached the contrary conclusion at [122]-[124] when dealing with the construction issue (see [86] above), on the basis that the word “pharmaceutical”, as used in each claim, imports these limitations.
2. The appellants submit that the primary judge’s finding in relation to the construction issue was in error because the word “pharmaceutical” does not have the meaning that the primary judge attributed to it: Ground 4. However, if claims 19 and 20 are limited to tablets prepared using the process described in the specification (where carbidopa is separated from levodopa and entacapone), then the primary judge ought to have found that the Actavis products do not infringe claims 19 and 20: Ground 7.
3. With respect to claim 21, the appellants say that the primary judge found at [182] (see [112] above) that the claim is fairly based because of its limitation of comparable therapeutic efficacy. The appellants submit that this finding does not address the substance of their fair basis case. The appellants also submit that, once again, the primary judge impermissibly imported the substance of the claim into the matter described in the specification, for the purpose of undertaking the comparison required by s 40(3) of the Act.

## Consideration

1. We are not persuaded that the primary judge erred in his conclusion that each of the impugned claims is fairly based on the matter described in the specification, although we would not agree with all aspects of his Honour’s reasoning in coming to that conclusion.
2. In their submissions, the respondents emphasise a number of other passages in the specification that describe the invention. When these passages are considered with the passages on which the appellants place particular reliance, we are led to conclude, as the primary judge did at [71], that the invention described is a new, oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa with at least one pharmaceutically effective excipient. The invention includes methods of preparing such a composition and a method of using such a composition, namely in the treatment of Parkinson’s disease.
3. The identification of the invention, in these terms, can be seen from the opening statements of the specification that describe the field of the invention: see [14] above. It can also be seen from the passage we have quoted at [19] above, particularly in the first paragraph thereof. The second paragraph of that passage explicitly refers to the three-in-one composition as “a composition according to the invention”.
4. We do not accept the appellants’ submission that the “preferable” stability and bioavailability characteristics and ease of swallowing, to which reference is also made in the second paragraph of the passage, are essential features of the invention that is described. This part of the description is best understood as referring to embodiments of the invention that can exhibit these preferable attributes. The embodiments are described in later passages of the specification and can be seen as exemplifications of what the specification says are the “particularly interesting properties” of the three-in-one composition.
5. Although the appellants urge a contrary view based on the distinction between the invention having “preferable” characteristics, as stated in the specification, and the invention “preferably” having these characteristics, we accept the respondents’ submission that this argument is really an “overly meticulous verbal analysis” of the kind eschewed in *Lockwood* at [68]; see the discussion in *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260;   
   [1994] FCA 396 at 275-282, especially at 281B-D.
6. This identification of the invention is supported by the statement, made in the description of the background to the invention, that no known publication describes an oral solid composition comprising entacapone, levodopa and carbidopa or their pharmaceutically acceptable salts or hydrates: see [16] above.
7. This identification of the invention is also supported by the general structure of the specification and the language employed in describing various embodiments of the invention.
8. For example, when introducing the separation of carbidopa from entacapone and levodopa, the specification says that “a particularly interesting way to increase the bioavailability of carbidopa from an oral solid composition comprising entacapone, levodopa, and carbidopa” has been found: see [24] above. This emphasises the fact that the “preferable” bioavailability characteristics are characteristics that can be attained if “a composition according to the invention” is prepared in a particular way. Later passages in the specification refer to the separation of carbidopa from entacapone and levodopa as a “preferred way to increase the bioavailability of carbidopa from an oral solid composition comprising entacapone, levodopa and carbidopa”: see [37] above.
9. As the respondents correctly point out, the specification does not say that a three-in-one composition must be formulated in this way, or indeed in any particular way, to achieve useful carbidopa bioavailability. This is because the bioavailability of carbidopa was found to be acceptable with Formulation 2, in which tablets were prepared by dry granulating (compaction granulating) all the active agents at the same time (see [30] above). Although the use of polyethylene glycol was found to cause stability problems, the fact remains that the acceptability of Formulation 2, in terms of the bioavailability of carbidopa, supports the conclusion that it is not an essential feature of the invention that carbidopa be separated from entacapone and levodopa in a three-in-one composition.
10. With regard to the compatibility of ingredients, the specification discloses that three-in-one compositions of the active agents containing MCC, surface-active substances or silica will have a stability problem. The specification describes the problem in terms of long term storage. Specific reference is made to Formulation 2, although this formulation must have been sufficiently stable to achieve the useful carbidopa bioavailability reported in Example 1. Importantly, however, the specification describes a three-in-one composition which does not include MCC, surface-active substances or silica as only a preferred embodiment: see [44] above.
11. Interestingly, the specification also refers to this combination as, specifically, “a *stable* oral solid pharmaceutical composition” (emphasis added). The consistory statement for claim 11 also describes the particular composition, there referred to, in the same way:   
    see [41]-[42] above. The word “stable” is also used to define the oral solid composition claimed in claim 11, whereas the other product claims simply refer to “an oral solid composition”.
12. Leaving aside the question of what meaning is to be given to the word “stable” in claim 11—a question which does not arise on this appeal—these aspects of the description in the specification serve to underscore the fact that the invention is the three-in-one composition to which we have referred and that the exclusion of incompatible excipients, which may cause long term storage problems, is not an essential feature of the invention, even though preferred embodiments will exclude such excipients.
13. As the respondents correctly point out, the specification proceeds by describing various embodiments of the invention which are subsequently claimed. In doing so, the specification can be seen to contain a number of consistory statements. We have identified some of these statements in our review of the specification at [14]-[67] above. We refer in particular to the consistory statement for claim 17 (see [55]-[56] above), which also supports claim 18 (insofar as it is dependent on claim 17); the consistory statement for claim 19 (see [58]-[59] above); the consistory statement for claim 20 (see [60]-[61] above); and the consistory statement for claim 21 (see [49]-[50] above), which also supports claim 22 (insofar as it is dependent on claim 21).
14. We accept the respondents’ submission that the consistory statements provide clear, discrete and self-contained disclosures of particular embodiments of the invention. We also accept the respondents’ submission that these embodiments are not interdependent. For example, the consistory statements that describe, on the one hand, embodiments of carbidopa separation, and the consistory statements that describe, on the other hand, the choice of excipients, are not cross-referenced or expressed to be mutually dependent. Thus, we accept the respondents’ submission that the relevant claims of the patent are directed separately to certain discrete, preferred aspects and embodiments of the invention, with different features limiting different claims.
15. In reaching our conclusion, we accept that there are passages in the specification which, when considered either individually or together, support the interpretation for which the appellants contend. However, these passages must be read with the other passages to which we have referred. As we have said, when this is done, we are led to conclude that the invention described is the three-in-one composition for which the respondents contend.
16. Contrary to the appellants’ submission, we do not accept that the specification should be read as proceeding from the starting point that the invention seeks to overcome the three problems identified by the appellants. We accept the respondents’ submission that the specification proceeds from the starting point that, prior to the invention, no oral solid composition comprising entacapone, levodopa and carbidopa, or pharmaceutically acceptable salts or hydrates of those active agents, in combination, had been described and that such a combination is useful in the treatment of Parkinson’s disease by assisting with patient compliance.
17. Our conclusion on the identification of the invention that is described in the specification is determinative of the question of fair basis that is raised in the appeal. This is because the appellants’ contention depends on an acceptance of the proposition that the matter described in the specification is a three-in-one composition of pharmacologically effective amounts of entacapone, levodopa and carbidopa in which a substantial portion of carbidopa is separated from the entacapone and levodopa and in which incompatible excipients are excluded. We have rejected that proposition. The specification certainly describes three-in-one compositions of pharmacologically effective amounts of entacapone, levodopa and carbidopa in which a substantial portion of the carbidopa is separated from entacapone and levodopa. It also describes three-in-one compositions of pharmacologically effective amounts of entacapone, levodopa and carbidopa in which incompatible excipients are excluded. But, as we have concluded, these are only particular embodiments of the invention that is more broadly described.
18. Having reached this conclusion, for the reasons we have stated, it is not necessary for us to deal with each of the appellants’ arguments that seek to challenge the primary judge’s reasoning. However, it is necessary for us to say something about the construction of claims 19 and 20 in response to the appellants’ submissions recorded at [130]-[133] above.
19. Claims 19 and 20 are to particular dosage forms (tablets) of the three-in-one composition. Those claims are not limited to tablets in which a substantial portion of the carbidopa is separated from entacapone and levodopa or in which the identified incompatible excipients are excluded. The primary judge reached the same conclusion at [164] and [174] when dealing with the question of fair basis. The appellants submit that the primary judge reached the contrary conclusion at [122]-[124] when considering the construction of claims 19 and 20.
20. Despite the respondents’ explanation of the primary judge’s reasoning, we are inclined to the view that his Honour did express a conclusion at [122]-[124] that was contrary to the conclusion his Honour expressed at [164] and [174]. However, we need not explore that matter further because nothing turns on it for the purposes of this appeal. This particular issue is only raised by the appellants to support their contention that claims 19 and 20 are not fairly based (Ground 4) or, conversely, to avoid a finding of infringement (Ground 7). We have rejected the appellants’ fair basis contention, but not on the basis of the construction of claims 19 and 20 apparently adopted at [122]-[124] of his Honour’s reasons. We have rejected the appellants’ fair basis contention because of our conclusion on the corresponding scope of the matter described in the specification. Once it is accepted that claims 19 and 20 are not limited to tablets in which a substantial portion of the carbidopa is separated from entacapone and levodopa or in which the identified incompatible excipients are excluded, the appellants’ infringement argument falls away.
21. We should also briefly address the appellants’ submissions recorded at [134] above in respect of claim 21. It is not apparent to us that the primary judge erred in the way alleged by the appellants (that is, by importing claim 21 into the description itself). We also fail to see how the primary judge’s reasons at [182] do not address the fair basis case that the appellants advance.
22. Claim 21 is a claim limited by result. It is supported by the consistory statement at page 13, lines 12-21 of the specification (see [49]-[50] above). This consistory statement is made in the context of the specification discussing a composition of the invention having similar therapeutic efficacy to known separate formulations of entacapone tablets and levodopa/carbidopa tablets. The specification then discusses preferred embodiments of the invention that have similar therapeutic efficacy to specific formulations of entacapone and levodopa/carbidopa. The description in the specification provides formulations (Formulations 3 and 4 in Example 2) that achieve the result that claim 21 asserts. These formulations do involve the separation of carbidopa from entacapone and levodopa. They also exclude unacceptable excipients. But in claiming the result of similar therapeutic efficacy, claim 21 is not required to be limited to these examples or, indeed, to any other preferred embodiment that is disclosed. In our view, the description in the specification plainly supports the invention that is claimed in claim 21 and claim 21 is fairly based on that description.
23. For these reasons, the grounds of appeal with which this contention is concerned must be rejected.

# The second contention: infringement of claims 17 and 18

## The appellants’ submissions

1. The appellants contend that the Actavis products do not fall within the scope of claim 17 or dependent claim 18, when those claims are properly construed.
2. When dealing with the construction issue, the primary judge found at [115]-[116]   
   (see [81]-[82] above) that step a) of the claimed method does not require the whole amount of the intended dose of entacapone and levodopa to be added at this point. The primary judge found at [114] (see [80] above) that it is enough if, for example, a pharmacologically effective, albeit low, dose of levodopa is added at this point, with the remainder of the intended dose of levodopa being added at step c), with carbidopa.
3. The appellants submit that the primary judge’s construction of claim 17 is inconsistent with a plain reading of the claim. The appellants submit that claim 17 is directed to a method characterised by four steps, which dictate the particular ingredients to be mixed, granulated, added or formulated in a particular sequence. The appellants submit that the primary judge’s construction effectively “neuters” the language of the claim.
4. The appellants submit that the primary judge’s reasons reflect a number of errors.
5. First, the appellants submit that the words “pharmacologically effective amounts” or “pharmacologically effective amount”, as used in claim 17, means the total dose of the active agents or agent to which the words are applied, multiplied by the total numbers of dosage forms being manufactured. The appellants argue that this meaning is consistent with other findings made by the primary judge.
6. Secondly, the appellants submits that the words “pharmacologically effective amounts” only appear at step a) and the words “pharmacologically effective amount” only appear at step c). The words do not appear in the chapeau to claim 17. If, for example, further amounts of entacapone or levodopa were to be added at step c), then there is no limitation on the amount of the active agent added at that step. This is because the words “pharmacologically effective amounts” only apply to entacapone and levodopa at step a). They do not apply to those active agents at step c).
7. Thirdly, the appellants note that the primary judge’s construction of claim 17 is based on the word “comprises” having an inclusive meaning where used in the chapeau to the claim. The appellants submit that, although the specification says (at page 25, lines 3-5) that the word “comprises” is “not intended to exclude other additives, components, integers or steps”   
   (see [64] above), the word “comprises” cannot function to enable the addition of steps or features that are otherwise excluded by the claim itself. The appellants submit that, if that were not the case, any words in the claim after the word “comprises” would not provide any limitation upon the claimed monopoly. The claim would be unclear or fail for want of definition (Ground 10).
8. The appellants also call in aid the use of the word “optionally” in step c) of the claim. They submit that the word “optionally” signifies the additions that can be made at this step—namely, the addition of a lubricant and one or more pharmaceutically acceptable excipients. There is no statement that additional levodopa, for example, can be added optionally at   
   step c). The appellants submit that to include the addition of levodopa at this step would be to create a different combination or method.
9. Fourthly, the appellants submit that, if claim 17 is construed in a way which does not require carbidopa to be added separately to entacapone and levodopa, the invention, so claimed, will not overcome the bioavailability problem. The appellants submit that the primary judge sought to overcome this difficulty by reasoning at [114] and [117] that levodopa might be added with carbidopa in step c) provided that the extra amount of levodopa, so added, does not affect the pharmacological efficacy of the total doses of all the active agents in the overall composition. The appellants submit that this reasoning is not supported by the description in the specification, which teaches the separation, in the three-in-one composition, of carbidopa from entacapone and levodopa.
10. Finally, the appellants note that there is no dispute that the Actavis products do not infringe claims 17 and 18 if the appellants’ construction of claim 17 is correct.

## Consideration

1. The consistory statement for claim 17 is found in that part of the specification that addresses tablet size: see [51]-[61] above. The specification says that the size of the fixed dose combination tablet comprising entacapone, levodopa and carbidopa prepared by compaction granulation can become too large for parkinsonism patients who have difficulties in swallowing. The specification teaches two processes which address this problem.
2. Broadly stated, the first involves the steps of mixing entacapone and levodopa with at least one excipient and optionally a disintegrant, and then granulating the mixture to obtain a granulated batch; mixing carbidopa with at least one excipient and optionally a disintegrant, and granulating the mixture to obtain a second batch; and then mixing the two batches with at least one excipient and optionally a lubricant to obtain a third mixture, which is then formulated into tablets. This process is the invention claimed in claim 16.
3. The second process is the invention claimed in claim 17. Broadly stated, this process involves the steps of mixing entacapone and levodopa with at least one excipient and a disintegrant, and granulating the mixture to obtain a granulated batch; and then adding carbidopa with, optionally, a lubricant and, optionally, one or more excipients to the granulated batch to obtain a second mixture, which is then formulated into tablets. It can be seen that, in this process, the carbidopa mixture is not granulated before it is mixed with the granulated entacapone/levodopa batch.
4. Claim 18 is expressed to be dependent on each of claims 16 and 17. It confines the granulation steps to wet granulation. Nothing turns on that limitation for the purposes of this appeal.
5. As we have noted (see [57] above), the specification teaches that, by using these processes, tablet compositions of the invention may be made which, for the dosages contained therein, are particularly small and convenient to administer.
6. These passages of the specification provide important context for the consideration of claims 16 and 17. Both processes speak of combining separate mixtures of entacapone/levodopa and of carbidopa, with each mixture being formed in a particular way. Each mixture is said to contain pharmacologically effective amounts of entacapone and levodopa or carbidopa, as the case might be, with the combination of the mixtures providing the composition which is then formulated into tablets.
7. The primary judge held at [111] that the expression “a pharmacologically effective amount” conveys “the meaning of an amount of the relevant [active agent] that ordinarily is known to be capable of producing a desired beneficial effect in the treatment of patients suffering Parkinson’s disease”. At [113], his Honour explained that the reason why an amount of one active agent is “pharmacologically effective” is because it is known to produce, in ordinary experience, a desired level or range of levels of the active agent in a patient’s blood plasma, bearing in mind that there is no uniquely correct amount for any state of Parkinson’s disease or uniformity of patient conditions or metabolisms. These findings are not disputed.
8. Bearing these matters in mind, it can be seen that each claim is directed to a specific process which will have the promised advantage of yielding a composition of the invention that provides tablets that are particularly small and convenient to administer and which contain pharmaceutically effective amounts of the active agents in question.
9. A plain reading of claim 17 (and claim 16) suggests that the process is one in which there is an intended pharmacologically effective amount of each active agent for each tablet to be made from the composition and that this pharmacologically effective amount is added at the designated process step specified in the claim.
10. The only reason to read the claim otherwise is to take the step that the primary judge took of giving the word “comprises” the meaning provided at page 25, lines 3-5 of the specification—namely, that its use in the description and claims of the specification “is not intended to exclude other additives, components, integers or steps”.
11. Undoubtedly, this indication in the specification must be borne in mind when construing claim 17. It cannot, however, contort the claimed process into a substantively different process. Put another way, the indication cannot give the word “comprise” and its variants an unbridled operation, when the relevant description and claims themselves specify, with appropriate precision, the step or steps to be taken that will provide the promised advantage.
12. For this reason, the better reading of claim 17 is that the word “comprises” must yield to the direction that the intended pharmacologically effective amounts of each active agent must be added at the step in the process that is specified for that addition. In our respectful view, the primary judge erred in construing claim 17 otherwise.
13. The respondents seek to uphold the primary judge’s construction of claim 17. They do so principally on the basis of the arguable scope of the word “comprises”, which we would reject. They also advance the primary judge’s reasoning at [114] and [117] to submit that the process of claim 17 would permit the addition off an extra ingredient, such as a further amount of levodopa, at step c). They submit that such a process would only be outside claim 17 if the added amount adversely affects the pharmaceutical efficacy of the composition.
14. In our respectful view, that reasoning cannot be employed. It proceeds on an acceptance that the process of claim 17 involves the addition of a pharmacologically effective dose of levodopa at step a) and the addition of a further pharmacologically effective dose of levodopa at step c)—the total amount of levodopa being, itself, a pharmacologically effective dose. It is possible, of course, that such a process might yield a composition that attains the promised advantage of providing tablets that are particularly small and convenient to administer and which contain pharmaceutically effective amounts of the active agents in question. But this is not one of the processes which the specification describes for attaining that advantage and, for the reasons we have given, it is not one of the processes that are claimed.
15. For these reasons, Grounds 3 and 6 of the appeal should be allowed.

# The third contention: lack of clarity or definition

## The appellants’ submissions

1. This contention raises two separate arguments.
2. The first is directed to claim 17 and concerns the word “comprises”: Grounds 3 and 10. This raises the same point of construction considered at [168]-[182] above.
3. The second argument is directed to claim 21 and concerns the primary judge’s construction of the words “comparable” when the claim compares the therapeutic effect of the claimed composition with the therapeutic effect of the known separate formulations of entacapone, levodopa and carbidopa: Grounds 5 and 11. The appellants submit that the primary judge erred by construing “comparable” as meaning “equivalent”, whereas the description in the specification uses synonyms for “comparable” (in the context of “comparable therapeutic effect”) such as “similar” and “substantially bioequivalent”. The appellants submit that had “equivalence” been intended, then the description in the specification would have said so.
4. The appellants accept that the words “equivalent therapeutic effect” would reflect a standard and, it would seem, provide clarity to claim 21. They submit, however, that this was not the language chosen in the claim. The appellants submit that the effect of the primary judge’s construction is to substitute a narrower standard (not used in the claim) for the broader language of “comparable therapeutic effect” (which is used in the claim).
5. The appellants then ask with respect to the allegedly broader language: “comparable” to what standard? The appellants submit that the boundaries of claim 21 are “opaque”.

## Consideration

1. Claim 17 does not lack definition and is not unclear. It has the meaning we have given at [176] above. Grounds 3 and 10 of the appeal must be rejected.
2. Similarly, claim 21 does not lack definition and is not unclear. It seems that only one expert witness (Dr Reece) expressed any difficulty in understanding the comparison required by this claim. The primary judge rejected Dr Reece’s evidence in this regard, noting that Dr Reece himself had spoken of comparable therapeutic efficacy when discussing two pieces of prior art in the joint experts’ report.
3. The specification makes clear the intended meaning of “comparable” in claim 21 when it is used in relation to therapeutic efficacy. The consistory statement for claim 21 says that the therapeutic effect achieved by the composition in the treatment of Parkinson’s disease will be “comparable” to that achieved with the known separate formulations of entacapone, levodopa and carbidopa if the therapeutic effect is “similar” (see [49] above).
4. We reject the appellants’ submission that the primary judge treated “comparable” as meaning “equivalent”. Indeed, at [128] his Honour found that the person skilled in the art would understand that the comparison required by claim 21 was of the respective efficacies of the three-in-one composition and the existing reference products (with similar administered amounts of the three active agents) to achieve a *similar* amount of levodopa crossing the blood-brain barrier. This finding was completely in accord with the teaching of the specification. There is nothing in his Honour’s reasons to indicate that he departed from that understanding in construing the claim.
5. His Honour correctly concluded at [130] and [135] that the assessment of comparability required by claim 21 is one that involves questions of fact and degree, and that the person skilled in the art would have little difficulty in making that assessment, which can be undertaken by reference to objective criteria. This finding is in accordance with the weight of the expert evidence. We can see no error in his Honour’s reasoning or conclusion.
6. For these reasons, Grounds 5 and 11 must also be rejected.

# The fourth contention: standing to sue

## The 2014 licence

### Introduction

1. Novartis claims, and the primary judge accepted, that it is an exclusive licensee for the purposes of s 120(1) of the Act, with the right to sue the appellants for infringement of the patent. Novartis says that its status as an exclusive licensee derives from the 2014 licence.
2. Schedule 1 of the Act defines the expression “exclusive licensee” as follows:

***exclusive licensee*** means a licensee under a licence granted by the patentee and conferring on the licensee, or on the licensee and persons authorised by the licensee, the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons.

1. For the reasons we will summarise below, the appellants contend that Novartis does not fall within this definition.
2. In order to understand the commercial and legal setting for the 2014 licence, and the rights it confers, it is necessary for us to summarise certain antecedent agreements between Novartis and Orion.

### The commercial dealings between the parties

1. On 7 September 2000, Orion and Novartis entered into certain “license, supply and distribution agreements”. Relevantly to this appeal, one of those agreements was for a territory designated as the “rest of the world” (**ROW**) (that is, territories other than Europe and the United States of America) (**the ROW agreement**).
2. Broadly speaking, clause 2.1 of the ROW agreement granted Novartis the exclusive rights to import, use, offer to sell, and sell in Australia and other places, any and all orally administered dosage forms of entacapone, levodopa and carbidopa that were formulated and manufactured by Orion (**the product**), including in a ready to use, packaged form with labels, inserts and leaflets, as applicable (**the finished product**). The particular finished product supplied to Novartis under the ROW agreement is called Stalevo.   
   The ROW agreement also included an exclusive licence of Orion’s patent rights to exploit the product, subject to the reservation, in clause 2.4, of Orion’s right to manufacture it.
3. The ROW agreement contemplated that Novartis might market its own product in competition with Orion’s product. Under clause 6.1(d), Orion could terminate the agreement, on notice, if this occurred. A similar right was provided under clause 16.2(a).
4. On 23 September 2010 and on 2 July 2012, Orion and Novartis entered into agreements which amended the ROW agreement. The amendments are of some importance to the appellants’ arguments as to how they say the 2014 licence should be characterised.
5. The agreement of 23 September 2010 was expressed to have effect from 1 January 2010. It extended the term of the ROW agreement. It also provided for a new clause 9.3.1. So far as relevant, the effect of the new clause was that, should any third party obtain regulatory approval for a generic product containing entacapone, levodopa and carbidopa during the extended term, Orion could, on certain terms, discuss supply with the third party. Orion could also commence marketing its own generic combination product where a third party had obtained regulatory approval in a particular part of the ROW territory for such a product and had not been prevented from commercialising that product in that part of the territory. In that event, Orion could also sell “relevant active substances” to any third party for that part of the territory.
6. The further amending agreement of 2 July 2012 recognised that Orion was not impeded from entering into a licence, supply and distribution agreement with a specifically named company or one of its affiliated companies with regard to the commercialisation of the product as a generic product in any of the countries covered by the ROW territory: see clause 3.8 thereof.
7. Such an agreement has been entered into. It was entered into after the 2014 licence. Under that agreement, the named company and its affiliates are granted the right to market the product as a generic product in, say, Australia in the event that a third party lawfully obtains regulatory approval, and is not prevented from commercialising, in Australia, a generic product containing entacapone or a fixed combination product comprising entacapone, levodopa and carbidopa. Upon the expiration or termination of that agreement, the company and its affiliates are free to continue to commercialise any competing product. If this occurs, Orion will not exercise its rights of termination in the relation to the ROW agreement. It is important to note that the events discussed in this paragraph are all events that could occur during the term of the patent.
8. On 3 December 2013, Orion and Novartis entered into a Confirmatory Licence Agreement (**the 2013 licence**). The recitals to the 2013 licence recorded Novartis’ wish to confirm the terms of the ROW agreement, as amended, for the purpose of Novartis being registered as the exclusive licensee of certain patent rights, including in respect of the patent in Australia. Before the primary judge, it was common ground that the 2013 licence did not confer on Novartis the right to manufacture the three-in-one composition, which had been reserved to Orion under the ROW agreement.
9. On 4 December 2013, Novartis entered into a sub-licence with Novartis Australia of the rights which Novartis had under the 2013 licence (**the 2013 sub-licence**).
10. On 5 December 2013, Orion, Novartis and Novartis Australia commenced their infringement proceeding against the appellants. Novartis and Novartis Australia relied on the 2013 licence and the 2013 sub-licence for their standing to sue. In particular, Novartis claimed to be the exclusive licensee of the patent, by reason of the 2013 licence.
11. As the primary judge recorded in Reasons 3 at [25], at the time of the commencement of the infringement proceeding, there were conflicting authorities as to what sufficed to create the status under the Act of an exclusive licensee. Given Orion’s reservation of its manufacturing right under the patent, the appellants argued that Novartis could not be an exclusive licensee for the purposes of the Act. In this connection, the appellants based their challenge on the decision in *Bristol-Myers Squibb Co v Apotex Pty Ltd* *(No 5)* (2013) 104 IPR 23;   
    [2013] FCA 1114 at [433]-[436] which had been given shortly before the commencement of the infringement proceeding. The judgment in that case was subsequently affirmed on appeal: *Bristol-Myers Squibb Company v Apotex Pty Ltd* (2015) 228 FCR 1;   
    [2015] FCAFC 2 (***BMS v Apotex***). By the time of the hearing before the primary judge, it was not in dispute that Orion’s reservation of its manufacturing right under the patent meant that Novartis could not be an exclusive licensee.
12. The primary judge found that the appellants’ challenge to the standing of Novartis’ and Novartis Australia’s standing to sue for infringement explained the reason why the 2014 licence and the 2014 sub-licence were entered into.

### The terms of the 2014 licence

1. It is convenient to set out the recitals to, and certain clauses of, the 2014 licence:

**RECITALS**

A Orion is the registered proprietor of Australian Letters Patent No. 765932, entitled “Levodopa/carbidopa/entacapone pharmaceutical preparation   
(**“the Patent”**). The Patent relates to new pharmaceutical compositions comprising entacapone, levodopa and carbidopa, or a pharmaceutically acceptable salt or hydrate thereof, to a preparation method of the compositions, to a use of the compositions in a therapeutic method and to the use of entacapone, levodopa and carbidopa, or their pharmaceutically acceptable salts or hydrates, in the manufacture of an oral solid fixed dose composition.

B The Licensee is the exclusive distributor in Australia of the levodopa/carbidopa/entacapone combination product Stalevo, derived from Orion or parties authorised by Orion (**“the Product”**).

C Orion wishes to formalise an exclusive licence of the Patent in relation to the Product.

**AGREEMENT**

1. Orion hereby grants to the Licensee, which accepts, an exclusive licence under the Patent from the date of the grant thereof to exploit (as that term is defined in Schedule 1 to the *Patents Act 1990*) the patented invention claimed in the Patent throughout the patent area (as that term is defined in Schedule 1 to the *Patents Act 1990*) to the exclusion of all other persons (**“Exclusive Licence”**).

2. In consideration for the rights granted under this Exclusive Licence, the Licensee undertakes to purchase the Products and the active ingredients that are contained in the Products, exclusively from Orion or a party authorised by Orion.

3. The Licensee is given full powers to have this Exclusive Licence registered by the Commissioner of Patents. The cost of registration shall be the responsibility of the Licensee.

…

6. The Licensee shall have the right to sub-licence to its related bodies corporate its rights under this agreement but shall otherwise not assign, transfer, mortgage, charge or part with any of its rights, duties or obligations under this agreement or grant any sub-licence without the prior written consent of Orion.

1. A side letter dated 6 March 2014, from Novartis to Orion, stated:

The purpose of this letter is to record the acknowledgement of Orion and Novartis that should the [ROW agreement] regarding the territory of Australia be terminated in accordance with its terms or by other mutual agreement, the Exclusive Licence is also terminated at that time.

### The primary judge’s reasons

1. The appellants’ case before the primary judge was that clause 2 of the 2014 licence qualifies clause 1, with the consequence that Orion had reserved for itself the exclusive right under the patent to manufacture the product. The appellants argued that, in this respect, the 2014 licence is no different to the ROW agreement as amended. The appellants said that the letter of 6 March 2014 confirmed this construction by interlinking the right to terminate the ROW agreement with the right to terminate the 2014 licence. The appellants also relied on the reference in Recitals B and C and clause 2 of the 2014 licence to “the Product” and argued that the 2014 licence was only confirmatory of Novartis’ existing distributorship rights under the ROW agreement. The appellants argued that Orion could terminate the ROW agreement under clause 6.1(d) and clause 16.2(a) if Novartis were to manufacture the product. The 2014 licence would terminate concurrently.
2. The primary judge was not persuaded by these arguments. His Honour reasoned that, in clause 1 and clause 6, Orion and Novartis had chosen the defined terms of the Act to express the nature and extent of the exclusive licence created by the 2014 licence. In particular, clause 6 of the 2014 licence recognised, as the definition of “exclusive licensee” in the Act recognises, that Novartis could sub-licence its rights. Clause 3 also contemplated that the 2014 licence would be registered under the Act as an exclusive licence, as required by s 187(1) of the Act and reg 19.1(a) of the *Patents Regulations 1991* (Cth).
3. His Honour also noted that the 2014 licence was entered into to meet the potential legal deficiencies of the 2013 licence. His Honour reasoned that the deliberate use of the statutory language pertaining to an exclusive licensee in clause 1 of the 2014 licence must have been intended to convey that Novartis would have the rights of an exclusive licensee as defined in the Act. The primary judge also reasoned that the commercial result which Orion and Novartis must have had in mind was that Novartis would have title to sue the appellants for infringement.
4. The primary judge rejected the appellants’ argument that clause 2 of the 2014 licence operated in derogation of what was otherwise the plenary nature of the rights granted by clause 1. His Honour reconciled clause 1 and clause 2 on the basis that, although a contract for the supply of goods of the kind envisaged by clause 2 might have the legal effect of constraining the licensee’s freedom to choose how to exploit the patented invention, the rights under clause 1 remained. Novartis’ rights under clause 1 were no less than if Novartis had contracted with a third party supplier in terms of clause 2 to secure the wherewithal to exploit the invention, rather than contracting with Orion. His Honour saw clause 1 and clause 2 as independent promises. At [49] of Reasons 3, his Honour said:

The consideration for the grant of the licence was Novartis’ promise to purchase Stalevo products and the 3 APIs exclusively from Orion. However, the interaction between the grant of the rights in cl 1 and the consideration promised in cl 2 is that each is a separate promise by one party to the other, creating rights and obligations that depend for their legal efficacy on the mutuality of those promises with the others in the other operative clauses. That is, reading the 2014 licence as a whole and in the commercial context in which it was made, the plenary grant of rights in cl 1 was the price Orion was willing to pay in consideration of Novartis’ promise to make the particular kinds of purchase specified in cl 2.

1. The primary judge did not see the words “in relation to the Product” in Recital C as having the effect of confining the scope of the grant in clause 1. At [51] of Reasons 3, his Honour noted that Orion and Novartis were in an existing commercial relationship with respect to the product and that they contemplated that they would continue in that relationship, even though the 2014 licence would alter or add features to that relationship. As his Honour saw it, Orion and Novartis intended to bring about the commercial result that Novartis could exercise the rights of an exclusive licensee, including the right to bring the infringement proceeding.
2. At [54]-[56] of Reasons 3, the primary judge turned to consider Novartis’ legal position in the event that it breached clause 2. The primary judge noted that if Novartis breached clause 2 by purchasing “the Products and active ingredients that are contained in the Products” from another source, it would have done so nonetheless in exploitation of its rights under clause 1. Put another way, Novartis may have acted in breach of clause 2, with the consequence that Orion could terminate the 2014 licence on account of that breach, but in so acting Novartis would not have infringed the patent given its rights under clause 1.
3. At [57] of Reasons 3, the primary judge concluded:

In those circumstances, there is no reason to arrive at the construction of the 2014 licence that [the appellants] propounded. Such a construction would require cl 1 to be read down and in a way that would negate the only reason why, in the circumstances, Orion and Novartis wanted to enter into the 2014 licence, namely to give Novartis the actual rights of an exclusive licensee ...

### The appellants’ submissions

1. The appellants submit, firstly, that the primary judge erred in finding that clause 1 and clause 2 of the 2014 licence are independent promises. The appellants say that clause 2 of the 2014 licence obliges Orion to manufacture the Stalevo product and supply it to Novartis. Under the ROW agreement, this manufacture can take place anywhere in the world, including Australia. The appellants say that, in this way, Novartis is precluded from exercising “the full breadth of rights” of the patent monopoly.
2. In this connection, the appellants argue that clause 2 of the 2014 licence is analogous to an exclusion clause or limitation clause that limits the rights that Novartis would otherwise have under clause 1. They also argue that there is an expressed dependency between the two clauses in light of the fact that Novartis’ promise in clause 2 is the consideration given for Orion’s grant of rights in clause 1. The appellants say that Recital C in the 2014 licence identifies the connection between the licence and the Stalevo product.
3. Secondly, the appellants challenge the primary judge’s reasoning based on the argument that Novartis’ rights under clause 1 are no less favourable than if Novartis had contracted with a third party for supply in terms of clause 2. The appellants submit that this example is not apposite because, if Novartis were to enter into such an arrangement, it would necessarily be in the nature of a sub-licence of its rights under the exclusive licence. They submit, however, that clause 2 of the 2014 licence is not of that nature. Orion is not acting under Novartis’ authority (as the third party supplier would be) but as the patentee who is conferring certain rights of exploitation on its licensee, while at the same time excluding other rights of exploitation.
4. Thirdly, the appellants submit that the primary judge failed to construe the 2014 licence in the context of the whole of the arrangement between Orion and Novartis, which included not only the ROW agreement but also the letter of 6 March 2014. They argue that the primary judge failed to give “due regard” to the rights of termination provided by clause 6.1(d) and other clauses of the ROW agreement should Novartis, itself, manufacture the product.
5. In this connection, the appellants stress the long-term nature of the ROW agreement—the agreement having been entered into on 7 September 2000 and extended to 31 July 2017—which, the appellants say, is a “high value” contract which reflects “a commercial balance on a number of issues”. Here, the appellants point to a number of provisions of the ROW agreement concerning Novartis’ obligations to pay certain upfront licence fees and milestone payments; to maximise sales and to meet minimum sale requirements; to comply with certain advertising and promotion objectives, which include identifying Orion as the manufacturer of the product; and to market the product under a trade mark chosen by Orion. The applicants also point, again, to the termination provisions in the ROW agreement should Novartis manufacture a competitive product, and to provisions which enable Orion to manufacture, in Australia, the Stalevo product.
6. Relatedly, the appellants submit that the primary judge also failed to take into account the effect of the amendments made to the ROW agreement, discussed at [201]-[203] above. The appellants say that Orion’s rights that were recognised by these amendments and the agreement subsequently made by Orion for the supply of a generic version of the product are inconsistent with Orion having granted, by the 2014 licence, an exclusive licence to Novartis to exploit the patent.

### Consideration

1. It is correct to say that the contractual arrangements between Orion and Novartis, which preceded the 2014 licence, created or recognised rights to exploit a three-in-one combination product in Australia that are, in legal effect, although not necessarily in practical operation, inconsistent with the rights that are held by an exclusive licensee for the purposes of the Act. This was obviously understood by Orion and Novartis following the Full Court decision in *BMS v Apotex*.
2. It is also correct to say that the agreement subsequently made by Orion for the supply of a generic version of the product creates rights that are, in legal effect, although not necessarily in practical operation, inconsistent with the exclusive rights which Novartis claims to hold under the 2014 licence.
3. It is difficult to see how these conflicting rights can be reconciled with the grant made under clause 1 of the 2014 licence, unless the 2014 licence is to be treated as a sham transaction or clause 1 is read down in some way to accommodate and thereby resolve the inconsistency.
4. Importantly, the appellants do not contend that the 2014 licence is a sham transaction: see *Sharrment Pty Ltd v Official Trustee in Bankruptcy* (1988) 18 FCR 449; [1988] FCA 266 at 453-458, 467-468. In that case, Lockhart J said (at 454):

A “sham” is therefore, for the purposes of Australian law, something that is intended to be mistaken for something else or that is not really what it purports to be. It is a spurious imitation, a counterfeit, a disguise or a false front. It is not genuine or true, but something made in imitation of something else or made to appear to be something which it is not. It is something which is false or deceptive.

1. The appellants do not contend, therefore, that the 2014 licence is a subterfuge for other, more limited, rights. However, they do contend that clause 1 should be read down as a matter of construction.
2. It is not apparent how this can be done. The words of the clause are abundantly clear. As the primary judge correctly observed, clause 1 invokes the definitions used in the Act with respect to the word “exploit” and “patent area” and it is manifest that the rights that were granted were intended to be exclusive in the sense that they were granted to Novartis to the exclusion “of all other persons”.
3. The definition of “exclusive licensee” in the Act makes explicit that the exclusionary character of an exclusive licence covers “the patentee and all other persons”. Clause 1 of the 2014 licence does not, in terms, refer to the exclusion of Orion, but no point was made about that fact and there is no reason why the words “all other persons”, which are used in clause 1, should not be given full effect to place Orion with “all other persons” in the excluded class. This is particularly so in circumstances where, in light of the decision of *BMB v Apotex* and the appellants’ challenge to Novartis’ standing to sue, Orion and Novartis no doubt recognised the deficiencies of the 2013 licence and purposefully entered into the 2014 licence not only to cure those deficiencies but to ensure that Novartis had the status of an exclusive licensee under the Act. In our view, this background circumstance is of considerable significance. Indeed, regardless of the contractual arrangements that Orion and Novartis had made in the past, clause 1 of the 2014 licence is, on its face, unequivocal in its terms.
4. The existence of what might be conflicting rights conferred by Orion on another in respect of the supply of a generic product in an agreement post-dating the 2014 licence cannot change the effect of that licence. There has been no variation of the 2014 licence; and there is no reason to give the 2014 licence a scope that is more limited than its language bears, because of later conduct of one party to it involving a third party.
5. Further, we do not think that either the recitals or other clauses of the 2014 licence require clause 1 to be read down. First, there are other clauses which support the plenary grant of rights under clause 1. Clause 3 recognises that the 2014 licence is intended to be an exclusive licence for the purposes of the Act and to be registered as such. Clause 6 recognises the right to sub-licence which the definition of “exclusive licensee” in the Act recognises.
6. There are parts of the 2014 licence which might suggest the possibility of a contrary conclusion but, on final analysis, we do not think that they have that effect. Recital C speaks of formalising a licence in relation to “the Product” (that is, the Stalevo product supplied under the ROW agreement). This circumstance is plainly engaged by clause 2 of the 2014 licence, upon which the appellants place considerable significance. We are persuaded that the primary judge’s analysis of the relationship between clause 1 and clause 2 is correct. Although it is true to say that the two clauses are connected, we think that the primary judge was correct to conclude that they represent separate promises in the sense that clause 1 creates the plenary rights of an exclusive licensee and clause 2 reflects the agreement between the parties as to how Novartis will exercise its rights. We do not think that clause 2 acts as some exclusion clause or limitation clause in the way in which the appellants contend, such as to cut down the legal effect of the rights granted by clause 1.
7. Further, we do not think that the interdependence between the ROW agreement as amended, and the 2014 licence, in terms of termination, points to a different construction and, ultimately, a different characterisation, of the rights granted by clause 1. This is because there is nothing in the definition of “exclusive licensee” in the Act which requires such a licence to be of any specific duration or a licence that cannot be terminated by an agreed event.
8. For these reasons, we are of the view that the primary judge was correct to conclude that the 2014 licence is an exclusive licence for the purposes of the Act and that, from 7 March 2014, Novartis had standing to sue the appellants for infringement. It follows that Grounds 14 and 15 of the appeal do not succeed.

## The 2014 sub-licence

### Introduction

1. The 2014 sub-licence is in relevantly similar terms to the 2014 licence. By clause 1, Novartis granted an exclusive sub-licence to Novartis Australia of the right to exploit in the patent area the invention claimed in the patent. By clause 2, Novartis Australia gave an undertaking to purchase the product and the active ingredients contained in it exclusively from Orion or a party authorised by Orion. This undertaking matches Novartis’ identical undertaking in clause 2 of the 2014 licence. Clause 3 provided for registration of the 2014 sub-licence by the Commissioner of Patents.

### The primary judge’s reasons

1. It was common ground before the primary judge that Novartis Australia is not an exclusive licensee for the purposes of the Act. Nevertheless, by reason of the 2014 sub-licence, Novartis Australia has the exclusive right to exploit the invention claimed in the patent. The primary judge considered that Novartis Australia had standing to sue the appellants for infringement of the patent for the following reasons.
2. First, the primary judge held that s 120(1) of the Act is only permissive and does not preclude a person other than the patentee or exclusive licensee from bringing infringement proceedings. Section 120(1) of the Act provides:

Subject to subsection (1A), infringement proceedings may be started in a prescribed court, or in another court having jurisdiction to hear and determine the matter, by the patentee or an exclusive licensee.

1. Secondly, the primary judge reasoned that, as s 13(2) of the Act recognises that the exclusive rights granted to a patentee are capable of assignment, an exclusive licensee can assign its “statutory exclusive rights” to a sub-licensee. His Honour considered that the 2014 licence and the 2014 sub-licence involved an assignment of exclusive rights of property that consisted of the power to enforce a statutory monopoly in respect of the right to exploit the patented invention during the term of the patent. Thus, his Honour held that, by the 2014 sub-licence, Novartis Australia had received an assignment of Novartis’ exclusive rights to exploit the patented invention and that, as the legal assignee of a statutory right, Novartis Australia, together with its assignor Novartis and the patentee Orion, had title to sue the appellants.
2. Thirdly, the primary judge reasoned that, if neither a patentee nor exclusive licensee wished to bring infringement proceedings, an exclusive sub-licensee must be capable of enforcing the exclusive rights assigned to it. His Honour observed that in such a case, it would not be necessary for the sub-licensee to bring separate proceedings against its licensor and those above it in the chain of title, seeking to compel them to bring infringement proceedings. His Honour saw s 120(2) of the Act as a reflection of that principle:

If an exclusive licensee starts infringement proceedings, the patentee must be joined as a defendant unless joined as a plaintiff.

1. His Honour also reasoned that this would be the position in equity, where equity will assist the assignee of a chose in action to sue a third party: see *Norman v Federal Commissioner of Taxation* (1963) 109 CLR 9; [1963] HCA 21 at 27.
2. Fourthly, the primary judge noted that s 139(1) of the Act states that the patentee and any person claiming an interest in the patent as exclusive licensee “or otherwise” are parties to a proceeding under s 138 of the Act for revocation of a patent, amongst other identified proceedings. Thus, Novartis Australia would be, at least, a proper party to the appellants’ cross-claim for revocation of the patent.
3. His Honour held, at [64] of Reasons 3:

Here, the presence of Novartis Australia as an applicant ensured that all persons who might claim an interest recognised by the Act in the exclusive rights the subject of the patent in suit would be party to a decision of the Court as to the enforceability of those rights. In any event, Novartis Australia was a proper party to both the claim and cross-claim because the cross-claim for revocation sought to deprive it of the benefit of property rights, that ss 13(2) and 14 allowed it to enjoy by the assignment of the exclusive rights to exploit the patent pursuant to the 2014 sub-licence.

### The appellants’ submissions

1. The appellants submit the primary judge’s reasons in relation to Novartis Australia’s standing to sue reveal a number of errors.
2. First, the appellants submit that, contrary to the primary judge’s finding, s 120(1) of the Act only permits the patentee or an exclusive licensee to bring infringement proceedings. The appellants submit that the language of s 120(1) is both “permissive and specific”.
3. Secondly, the appellants submit that there is no other provision in the Act that permits an exclusive sub-licensee or sub-licensee to bring infringement proceedings.
4. Thirdly, the appellants submit that neither the 2014 licence nor the 2014 sub-licence provided for any assignment of rights. The appellants submit that clause 6 of the 2014 licence is explicit: Novartis had the right to sub-licence but not to assign any rights it held by virtue of the licence it had been granted. Similarly, by clause 1 of the 2014 sub-licence, Novartis granted a sub-licence. It did not purport to assign rights.

### Consideration

1. We commence our consideration by noting that the respondents do not seek to support the primary judge’s findings that Novartis Australia had standing to sue for infringement. They say that there is no dispute that Novartis Australia is not an exclusive licensee of the patent. They argue that, as the exclusive sub-licensee under the 2014 sub-licence, Novartis Australia is a proper party to at least the cross-claim for revocation of the patent, by dint of s 139(1) of the Act.
2. The respondents go further. They say that there is no need, on this appeal, to consider whether Novartis Australia has standing to sue for infringement. Nevertheless, the respondents also say that they do not oppose an order allowing the appeal to the limited extent of varying certain orders made by the primary judge on 4 December 2015 to reflect the date of commencement of the cross-claim; to delete reference to Novartis having standing to sue; and to provide that Novartis Australia’s costs be confined to those of the cross-claim only.
3. The respondents’ position is properly taken. We think that the primary judge erred in concluding that Novartis Australia had standing to sue for infringement. In our view, s 120(1) of the Act is clear on that subject. Although s 120(1) uses the word “may”, it is specific as to who may sue for infringement—the patentee or an exclusive licensee. We do not read s 120(1) as being merely indicative of the persons who can sue for infringement. The parties accept that Novartis Australia is neither the patentee nor an exclusive licensee.
4. Further, we accept the appellants’ submission that neither the 2014 licence nor the   
   2014 sub-licence involved an assignment of rights that effectively passed from Orion to Novartis Australia. Under the 2014 licence, Orion maintained its rights as patentee, including its right to sue for infringement. These rights were subject to Novartis’ rights as exclusive licensee, which were terminable by Orion. Nevertheless, as exclusive licensee, Novartis had, by operation of s 120(1) of the Act, standing to sue the appellants for infringement on and from 7 March 2014. As a licensee from Novartis, Novartis Australia was not an exclusive licensee (because it did not hold its licence from the patentee, Orion) and had no standing to sue the appellants for infringement. Nevertheless, it was a licensee of rights to exploit the patented invention. It therefore had an interest in the patent sufficient to engage s 139(1) of the Act and was a proper party respondent to the appellants’ cross-claim: *Emory University v Biochem Pharma Inc* (1998) 42 IPR 35; [1998] FCA 915 at 44-45.
5. It follows that Ground 16 of the appeal should be allowed.

# Conclusion and disposition

1. We have concluded that Grounds 3 and 6, and Ground 16, of the appeal should be allowed. Otherwise the appeal should be dismissed.
2. At the hearing of the appeal, the respondents handed up a draft of the orders they propose. The draft proposes variations to Orders 1 to 3 made by the primary judge on 4 December 2015 concerning the standing of Novartis and Novartis Australia to sue for infringement. The draft also includes orders for costs. The draft costs orders proceed, in part, on the assumption that, other than on the question of Novartis’ and Novartis Australia’s standing to sue for infringement, the respondents would be completely successful on the appeal.
3. The form of the proposed orders was addressed only very briefly by the appellants in submissions in reply. They submitted that Novartis Australia’s claim for infringement should be dismissed. We accept that this should be the case. The appellants also submitted that the respondents should pay their (the appellants’) costs of the appeal insofar as those costs concern the question of Novartis Australia’s standing to sue for infringement. The appellants can be seen as having success on that issue, but, having regard to the overall compass of the appeal, it does not following necessarily that costs should be apportioned or apportioned in this way. In any event, our conclusion concerning Grounds 3 and 6 also means that the appellants’ success has been greater that that contemplated by the respondents’ draft orders. The parties have not addressed us on how the burden of costs should fall in these circumstances. Further, it is apparent that other orders made by the primary judge will require variation in light of the conclusions we have reached.
4. Accordingly, the parties should attempt to agree on the orders that will give effect to these reasons. They should also attempt to agree on the question of costs. To this end, we will order that the parties bring in agreed orders by 4.00 pm on 23 September 2016. If the parties are unable to agree, they should provide drafts of the orders they propose, supported by written submissions not exceeding three pages in length, by 4.00 pm on 30 September 2016.
5. Finally, [94] and [95] of these reasons contain information that is confidential. We shall make orders preserving the confidentiality of that information in terms similar to the orders of the primary judge made on 16 September 2015.

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| I certify that the preceding two hundred and fifty-eight (258) numbered paragraphs are a true copy of the Reasons for Judgment herein of the Honourable Chief Justice Allsop and Justices Nicholas and Yates. |

Associate:

Dated: 9 September 2016

SCHEDULE OF PARTIES

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|  | NSD 1207 of 2015 |
| Appellants |  |
| Second Appellant | MEDIS PHARMA PTY LTD (ACN 109 225 747) |
| Respondents |  |
| Second Respondent | NOVARTIS PHARMA AG |
| Third Respondent | NOVARTIS PHARMACEUTICALS (AUSTRALIA) PTY LIMITED (ACN 004 244 160) |