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"Best Method" Requirement Increasingly Prominent in Australian Patent Disputes

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Authors:
Duncan Longstaff, Principal | Dr Doug Horton, Principal | Dr James Beckett, Patent Attorney

Australia is one of the few major patent jurisdictions which has maintained in its patent law a discrete requirement that a patentee disclose the "best method" known to it of performing the invention.

As outlined in our accompanying article, best method challenges have assumed an increasingly prominent role in Australian patent disputes and can significantly affect the conduct and strategy of Federal Court litigation, in particular.

The table below summarises the claims, findings and key issues of selected Australian patent cases where best method has proven a pivotal issue. Please click each case title to go to the judgment.

Potential patent litigants should be mindful of the substantive and procedural implications best method issues can have in the Australian iteration of global disputes. And in view of the increasing prominence of best method challenges, patent applicants should pay particular attention to this issue when filing and prosecuting patent applications in Australia, and especially when filing divisional applications.

Selected Australian patent cases involving Best Method challenges

Case	Claim(s)	Finding	Notable
Les Laboratoires Servier v Apotex Pty Ltd (2016) 247 FCR 61 (click each Case title for judgment)	1. The arginine salt of perindopril and its hydrates. 2. Pharmaceutical composition comprising, as active ingredient, the arginine salt of perindopril and its hydrates, in combination with one or more pharmaceutically acceptable excipients.	*"...in describing only the general method of classical salification rather than a specific method, such as the known 1986 and 1991 method, which would have provided the information to the skilled reader of a method for obtaining a form of perindopril arginine which met the characteristics of the claimed invention, Servier failed to describe the best method known to it of performing the invention".*	Evidence (of inventors) demonstrated **actual patentee knowledge of better methods not disclosed.** Amendment to introduce best method (pre-RTB s102) refused on discretionary grounds.

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GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No 2) Limited v Generic Partners Pty Limited (2018) 264 FCR 474	1. A pharmaceutical composition comprising a bilayer tablet having an immediate release phase of paracetamol and a sustained release phase of paracetamol, the immediate release phase being in one layer and comprising from about 10 to 45% by weight of the total paracetamol; and the sustained release phase being in the other layer and comprising from about 55% to 90% by weight of the total paracetamol in admixture with a matrix forming polymer or a mixture thereof; said composition comprising from 600 to 700mg of paracetamol per unit dose and a pharmaceutically acceptable carrier, wherein said composition has an in vitro paracetamol dissolution profile (as determined by the USP type III apparatus, reciprocating basket, with 250ml of 0.1M HCl at 37C set at a cycle speed of 15 strokes/min) with the following constraints: • 30 to 48% released after 15 minutes • 56 to 75% released after 60 minutes • >85% released after 180 minutes.	*"...we are not satisfied that the respondents discharged their onus of establishing that the Patent was invalid on the ground that the complete specification failed to specify the particular grade and viscosity of HPMC or granulation end points that might be used to perform the invention according to the best method known to the patent applicant. We agree with the primary judge that the best method was disclosed, albeit at a level of generality that did not include the more detailed but inessential manufacturing and production information described in the MAA applicable to the commercial embodiment."*	Patent survived best method challenge because details not disclosed were inessential to performance because they were common general knowledge / routine

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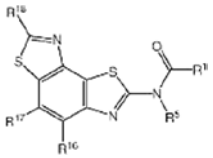
Kineta, Inc. [2017] APO 45 (31 August 2017)	Claim 1 as proposed to be amended is directed to a compound represented by the formula:  For the purposes of this decision it is not necessary to consider the definition of the variables R1, R5, R16, R17 and R18. Later claims are appended to claim 1 and directed to pharmaceutical compositions comprising the compound and methods of treatment comprising administering the composition.	*"The specification does not set out any method of preparing the compounds, and no method is apparent when the specification is read in the light of the common general knowledge. The applicant was aware that the compounds could be obtained from a commercial supplier. I am satisfied that the specification does not comply with section 40(2)(aa) as it does not disclose the best method known to the applicant."*	Patent applicant failed to disclose the best method of performing the invention because it had failed to disclose that the only method known to it of obtaining the compounds of the invention was to commission their synthesis from a particular supplier Patent Office decision upholding objection during examination
AUPharma Pty Limited v Mundipharma Pty Limited [2023] FCA 330	*"Each patent relates to an oral controlled-release pharmaceutical composition comprising oxycodone and naloxone, where the oxycodone and the naloxone are present in a ratio within the range of 5:1 to 1:1 (the 469 patent, the 453 patent, and the 011 patent), or within the range of 4:1 to 1:1 (the 745 patent and the 130 patent), and where the composition releases the oxycodone and the naloxone".*	The Court orders that: 1. The respondent produce to the applicant electronic copies of the following modules from the dossier provided to the Therapeutic Goods Administration in relation to each of the respondent's TARGIN® products: a) module 3.2.P.1 titled "Description and Composition of the Drug Product"; b) section 3.2.P.2.1 titled "Components of the Drug Product"; c) section 3.2.P.2.2 titled "Drug Product"; d) section 3.2.P.2.3 titled "Manufacturing Process Development"; and e) module 3.2.P.3.3 titled "Description of Manufacturing Process and Process Controls".	Discovery ordered with respect to specific sections of regulatory dossier where best method challenge related to details of pharmaceutical formulation, in the context of a challenge to a pharmaceutical patent term extension

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Novartis AG v Pharmacor Pty Limited (No 2) [2023] FCA 963	1. A pharmaceutical composition comprising: (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof; and (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)- p-phenylphenylmethyl)-4 amino-2R-methylbutanoic acid ethyl ester or (2R,4S)- 5-Bipheny-4-y-4-(3 carboxypropionylamino)-2- methyl-pentanoic acid or pharmaceutically acceptable salts thereof and a pharmaceutically acceptable carrier.	*"On balance, I am not persuaded that the just resolution of the substantive question raised by Novartis's separate question—namely, the date fixed by s 40(2)(a) of the Act (in its relevant form) for determining the patent applicant's knowledge of the best method—in accordance with the overarching purpose, favours the hearing of that question separately from and before any other question in the proceeding. I am satisfied that the substantive question is best determined in the context of the trial itself."*	Application by patentee, after giving discovery, for legal viability of specific best method challenge to be heard as a "separate question" before all other issues of validity and infringement refused by the Court
Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd (2017) 348 ALR 156	An extension drilling system for use with a semi-automatic drilling rig, said drilling system including a plurality of extension rods connected together to constitute a drill rod string and each extension rod having a male right-hand rope threaded coupling at one end and a female right-hand rope threaded coupling at the other end, whereby the extension rods are connected together by coupling of the male coupling of one extension rod with the female coupling of another extension rod to create a male/female coupling between extension rods, a drive chuck of a drilling rig for driving the outside surface of a female coupling of an extension rod at one end of the drill rod string, in either forward or reverse direction, a set of grippers for preventing rotation of an extension rod being arranged to clamp an extension rod at a location such that only one male/female coupling is located between the drive chuck and the set of grippers and so that with the grippers clamping the extension rod, and with the drive chuck being driven in the reverse direction, the male/female coupling between the grippers and the drive chuck is uncoupled.	*"…in assessing whether it was incumbent on Sandvik to describe the best form of sealing member known to it, one looks to the invention described in the specification. The invention is an extension drilling system as set out in [117] above. The question is whether the specification described the best method known to Sandvik of performing that invention. For the reasons given above, in our view, it did not."*	Evidence demonstrated common general knowledge that a seal was required at the point where a single-pass rod or an adaptor sits in the chuck. Despite not being an express feature of any claims, an effective seal was deemed part of the invention, or at least of performing the invention.

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Dometic Australia Pty Ltd v Houghton Leisure Products Pty Ltd (2018) 135 IPR 403	1. An air conditioning system for a vehicle having a roof, the air conditioning system having at least one air conditioning unit, including: • at least one centrifugal fan; • at least one return air entry port; • at least one outlet port; • at least one evaporator coil operatively connected to a compression refrigeration system; • a chamber formed by the at least one evaporator coil substantially surrounding the at least one centrifugal fan, the at least one centrifugal fan being operable to draw in indoor air via the return air entry port and eject the indoor air in a substantially horizontal plane such that it is forced into the at least one evaporator coil; and • a conditioned air flow path adapted to direct conditioned air from the chamber in a downward direction and towards the at least one return air entry port and then redirecting the air flow path outwards and away from the at least one return air entry port to exist the at least one outlet port in a substantially horizontal plane adjacent to the roof.	*The inventors "…did not include any accompanying description of the design, let alone an explanation concerning the requirement for the upper and lower surfaces of the outlets to be complementary. The two pages were a limited source of information only and, in my view, insufficient to indicate to the reader that the particular profile of the outlets had any significance in the performance of the air conditioning system. I consider that they would have been inadequate to convey to DometicSweden knowledge of the best method of performing the invention."*	The relevant date for assessing best method with respect to a divisional application is the divisional filing date (not parent filing date). Although evidence was adduced that a better method of performing the invention was developed by one of the inventors between the parent filing date and divisional filing date, this knowledge could not be attributed to the (lucky) patentee, which had already taken an assignment of the patentee at the divisional filing date but the inventors had not effectively communicated the better method they had developed to the new patentee.
BlueScope Steel Limited v Dongkuk Steel Mill Co Ltd (No 2) (2019) 152 IPR 195	A hot-dip coating method for forming a coating of a corrosion-resistant Al-Zn-Si-Mg alloy on a steel strip comprising passing the steel strip through a hot dip coating bath that contains Al, Zn, Si, and Mg and optionally other elements and forming an alloy coating on the strip with a variation in thickness of the coating of no more than 40% in any given 5 mm diameter section so that the distribution of Mg_2Si particles in the coating microstructure is such that there is only a small proportion of Mg_2Si particles or substantially no Mg_2Si particles in the surface of the coating.	*"The nature of the invention … is to [control] .. coating thickness variations … As stated in the specification, in order for that to be achieved "special operational measures" had to be applied. Accordingly, disclosure of these "special operational measures" had importance. In my view BlueScope was under an obligation to disclose the "special operational measures" known to it at the filing date to control short term coating variation."*	"I do not accept BlueScope's submission that a skilled addressee would understand that "*special operational measures*" meant the particular four operating measures known by BlueScope to be the best method of performing the invention as at the filing date."